IR BIOSCIENCES HOLDINGS INC
Form 10-K
May 24, 2011

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

FORM 10-K

x	Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the fiscal year ended December 31, 2010
	OR
o	Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

COMMISSION FILE NUMBER: 33-05384

IR BIOSCIENCES HOLDINGS, INC.
(Name of Small Business Issuer in its Charter)

DELAWARE (State or Other Jurisdiction of Incorporation or Organization)	13-3301899 (I.R.S. Employer Identification No.)
8777 E. Via de Ventura, Suite 280, Scottsdale, AZ (Address of Principal Executive Offices)	85258 (Zip Code)

(480) 922-3926
(Issuer's Telephone Number, including Area Code)

SECURITIES REGISTERED UNDER SECTION 12(B) OF THE EXCHANGE ACT:

NONE

SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE EXCHANGE ACT:

COMMON STOCK, $ 0.001 PAR VALUE PER SHARE
(Title of class)

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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

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

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

The aggregate market value of the registrant's issued and outstanding shares of common stock held by non-affiliates of the Registrant as of June 30, 2010 (based on the average of the bid and asked prices as reported by the FINRA OTC Bulletin Board as of that date) was approximately $2,224,985. Shares of common stock held by officers, directors and each shareholder owning ten percent or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates.

The number of shares of the Registrant's common stock outstanding as of May 20, 2011 was 17,082,963.

Documents Incorporated by reference: The information required by Part III of Form 10-K incorporated by reference from the Registrant's definitive proxy statement on Schedule 14A that will be filed no later than the end of the 120-day period following the Registrant's fiscal year end, or, if the Registrant's definitive proxy statement is not filed within that time, the information will be filed as part of an amendment to this Annual Report on Form 10-K/A, not later than the end of the 120-day period.

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EXPLANATORY NOTE

Due to financial constraints, the filing does not include an independent auditor's report and the financial statements are unaudited. The Company anticipates filing audited reports in the near future.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K, including the sections entitled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this annual report on Form 10-K, including statements regarding our future financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “believes,” “expects,” “anticipates,” “intends,” “estimates,” “may,” “will,” “continue,” “should,” “plan,” “predict,” “potential” or the negative of these terms or other similar expressions. We have based these forward-looking statements on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. Our actual results could differ materially from those anticipated in these forward-looking statements, which are subject to a number of risks, uncertainties and assumptions described in the “Risk Factors” section and elsewhere in this Form 10-K, regarding, among other matters:

- default on our senior secure debt obligations resulting in an intent to sell the collateral in public auction ;
- the substantial doubt about our ability to continue as a going concern as raised by our independent auditors;
- our lack of cash resources, lack of revenues and expectation to continue to incur substantial losses for the foreseeable future;
- our need for substantial additional funding;
- adverse general economic and financial market conditions;
- our dependence on our potential drug candidate, Homspera;
- uncertainty as to if we will be successful, if ever, in developing a product and receiving regulatory approval;
- our ability to protect our proprietary technology and potential costs involved;
- our dependence on our officers and key employees;
- our potential inability to repurchase our secured convertible notes;
- the conversion of our outstanding convertible notes would be dilutive and would adversely affect the market price of our common stock;
- the volatility of the price of our equity securities; and
- other factors referenced in this annual report on Form 10-K and other reports.

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You should not rely upon forward-looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, neither we nor any other person assume responsibility for the accuracy and completeness of the forward-looking statements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Form 10-K to conform these statements to actual results or to changes in our expectations.

You should read this annual report on Form 10-K, and the documents that we reference in this Form 10-K and have filed as exhibits with the Securities and Exchange Commission, completely and with the understanding that our actual future results, levels of activity, performance and achievements may materially differ from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

ADDITIONAL INFORMATION

We are required to file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings over the Internet at the SEC's Web site at http://www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, N.E. Washington, DC 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

We maintain a corporate Web site at www.immuneregen.com. You may access our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed with, or furnished to, the SEC pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, with the SEC free of charge at our Web site as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The reference to our Web address is provided for informational purposes only and does not constitute incorporation by reference of the information contained on this Web site.

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PART I

When we use the terms “IR BioSciences,” “we,” “us,” “our,” and “the company,” we mean IR BioSciences Holdings, Inc. a Delaware corporation, and its subsidiaries. Our principal subsidiary is our wholly-owned subsidiary, ImmuneRegen BioSciences, Inc. (“ImmuneRegen”).

ITEM 1. DESCRIPTION OF BUSINESS

We are a development-stage biotechnology company. Through the Company’s wholly-owned subsidiary ImmuneRegen BioSciences, Inc., the Company is engaged in the research and development of the potential drug candidate Homspera for use in innovative therapies in pulmonology, immunology and hematology. Pulmonology is the branch of medicine relating to the study and science of the anatomy, physiology, and pathology of the lungs, including diseases of the respiratory system. Immunology is the field of medicine relating to the study of all aspects of the immune system including its structure, function and disorders thereof. Hematology is the study of blood, the blood-forming organs, and blood diseases. ImmuneRegen’s strategy is to develop proprietary therapeutics through Phase I / II clinical studies while seeking out-licensing arrangements and collaborations with partners to complete development and achieve commercialization.

Currently, the Company’s primary efforts are focused on the research and development of therapies in the areas of pulmonary fibrosis, influenza infection and radiation-induced Neutropenia. Other areas of research include vaccine adjuvant activity evinced against certain forms of cancer and applications for wound healing and for regenerating or strengthening the human immune system, in part, through stimulating human adult stem cells. It is the belief of our management that the stem cell activity exhibited by Homspera underlies some of the effects previously reported in potential applications like treatment for radiation exposure and infectious diseases using Homspera derivatives Radilex and Viprovex, respectively, which are described below. In addition, we continue to explore the potential capabilities of Homspera and strive to better understand the mechanisms of this compound in order to further our development efforts with regard to not only our current application research, but also potential future applications.

Our patents, patent applications and continued research are partially derived from discoveries made during research studies related to the function of Substance P, which is found in the body and has a large number of actions. These studies were funded by the Air Force Office of Scientific Research (AFOSR) in the early 1990s and were conducted by research scientists, including our co-founders Drs. Mark Witten and David Harris. In the course of research on Substance P, scientists created a number of synthetic analogues, structural derivatives with slight chemical differences, for study. One of these, which we have named Homspera, is the basis for our drug development efforts and our intellectual property. All of our research and development efforts are at the pre-clinical stage and Homspera has only undergone exploratory studies to evaluate its biological activity in small animals. There can be no assurance that our interpretation of study results will prove to be accurate after further testing, and our beliefs regarding the potential uses of our drug candidates may never materialize.

It is important to note that the terms Homspera, Radilex and Viprovex refer to the same compound. Some experiments performed by the company have utilized different formulations and/or routes of administration, and the drug administered in these studies may be referred to by either name. However, it is not the active compound that differs, but only the route of administration and/or diluents used for formulation. All such studies inform and justify utility of the active ingredient Homspera.

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Studies have evaluated the effects of Homspera on human adult stem cell activity. Additionally, studies have been performed to evaluate the efficacy of Homspera as a potential product to increase the healing rate of wounds. One aspect of this evaluation is to consider the impact of Homspera on the mechanisms and pathology of fibrosis, which is associated with scar formation, and regarding pulmonary injury, which can occur following exposure to ionizing radiation (gamma rays or x-rays).

We are researching Radilex for use as a potential treatment for acute exposure to radiation. We also believe that a commercial market may exist for the use of Radilex as it relates to the amelioration of certain side effects of cancer treatments, whether chemotherapy or radiotherapy. These side effects, which include specifically neutropenia, cause management to believe that Radilex, if developed, may be an acceptable candidate to be marketed to governmental agencies for procurement into the Strategic National Stockpile for potential use following radiological or nuclear threats.

We are researching Viprovex for potential use in treatments of exposure to biological agents, such as infectious diseases, which include influenza and anthrax. We believe that potential commercial opportunities may exist for the treatment of seasonal influenza and other viral or bacterial infections, either as a stand-alone drug or as an adjuvant to other existing drugs. We believe that Viprovex, if adequately developed, may be used in potential applications for sale to governments for the treatment of exposure to anthrax and pandemic influenza. In addition, ongoing studies are being performed to evaluate the efficacy of Viprovex as a vaccine adjuvant to enhance immune response to a given dose of vaccine for either prophylactic protection, such as influenza, or therapy, such as cancer. Based on early studies on Homspera and existing literature on Substance P, we are also researching the efficacy of Viprovex as a potential treatment for exposure to chemical agents.

In May 2009, we submitted an Investigational New Drug Application (IND) to the U.S. Food and Drug Administration (FDA) to begin human clinical testing of Homspera to evaluate Homspera initially as a treatment for Idiopathic Pulmonary Fibrosis. Recently, we submitted an application for Orphan Drug Product Designation for Homspera for the application of treating Idiopathic Pulmonary Fibrosis. We have also submitted preliminary study data to the U.S. Food and Drug Administration (FDA) and have been issued two Pre-Investigational New Drug (PIND) numbers, one for the potential use of Radilex in the treatment of acute radiation syndrome (PIND 63,255) and the other for the potential use of Viprovex in the treatment of avian influenza (PIND 73,709). We have evaluated and/or contracted with a number of FDA regulatory consultants to assist us in our preparation and submission of an Investigational New Drug application, a necessary prerequisite to human clinical studies, which can only follow after the FDA's allowance of our IND.

To date, we have not obtained regulatory approval for, or commercialized any applications, using Homspera or any of its derivatives. We have incurred significant losses since our inception and we expect to incur annual losses for at least the next three years as we continue with our drug research and development efforts.

We have filed patent applications directed to various methods of using and compositions comprising Substance P analogues. As of December 31, 2010 we owned approximately fourteen issued patents, including three issued U.S. patents and eleven issued foreign patents. Also as of December 31, 2010 we had approximately twenty-three pending patent applications and twelve filed and waiting for review. All inventions embodied in these applications and issued patents have been assigned to the company by the inventors. In addition, we have entered into a license agreement with the University of Pittsburgh whereby we have licensed the University's ownership interest to a patent that was jointly filed with the University of Pittsburgh.

Our potential drug candidate Homspera is at a pre-clinical stage of development and may not be shown to be safe or effective in humans and may never receive regulatory approval. Homspera has not been tested in humans. There is no guarantee that regulatory authorities will ever permit human testing of Homspera, or any potential products derived

from Homspera. Even if such testing is permitted, neither Homspera, Radilex, Viprovex or any other potential drug candidates, if any, derived from Homspera may be successfully developed or shown to be safe or effective in humans.

The results of our pre-clinical studies and clinical trials may not be indicative of future clinical trial results. A commitment of substantial resources to conduct time-consuming research, pre-clinical studies and clinical trials will be required if we are to develop any commercial applications using Homspera or any derivatives thereof. It is possible that partnerships and/or licensing agreements will not develop during the preclinical and/or clinical stages of development, if at all. Delays in planned patient enrollment in our future clinical trials may result in increased costs, program delays or both. None of our potential technologies may prove to be safe or effective in clinical trials. Approval of the FDA, or other regulatory approvals, including export license permissions, may not be obtained and even if successfully developed and approved, our potential applications may not achieve market acceptance. Any potential applications resulting from our programs may not be successfully developed or commercially available for a number of years, if at all.

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SUBSTANCE P AND HOMSPERA™

Our patents, patent applications and continued research relate to Substance P and related substances. Substance P is found in the body and performs a large number of actions. Substance P analogues are structural derivatives with slight chemical differences from Substance P. One of these analogues of Substance P, which we have termed Homspera, is the basis for our research and development of potential drug candidates.

Substance P

The elements carbon, oxygen, nitrogen and hydrogen can be combined to form amino acids, the basic building blocks of life. When amino acids are combined through a biochemical process they form what are called peptides or proteins. Proteins play a number of fundamental roles in living organisms, from structural to messaging between cells. Neurotransmitters are chemicals that relay signals between neurons and other cells found throughout the body. When peptides are released by nerves or other cells and modulate this neurotransmission, they are termed neuropeptides.

One such neuropeptide is Substance P. Discovered in 1931, Substance P is a relatively small peptide made of just eleven amino acids. The amino acid sequence (using the standard three-letter acronyms for amino acids) of Substance P is presented below:

Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-NH2.

Neuropeptides, such as Substance P, were originally identified as being distributed throughout the peripheral and central nervous systems of experimental animals, and then of humans. To date, Substance P has also been shown to be produced in non-neuronal cells such as human endothelial cells, Leydig cells, enterochromaffin cells, epithelial cells, fibroblasts, keratinocytes, intestinal and airway smooth muscle cells, inflammatory and immune cells, and in cells of the female reproductive system.

In early research, Substance P was revealed as playing a key role in the transmission of pain. Later on, Substance P was identified as being involved in the pathophysiology of psychiatric disorders, like anxiety and depression. Additionally, Substance P has been shown to be involved in a number of physiological processes, such as blood vessel and smooth muscle contractions, and in the levels and responses of cells in the blood and immune system.

Substance P produces this wide variety of effects by acting through three different molecular receptors, located on the surface membrane of sensitive cells. These receptors are called NK1 (neurokinin 1), NK2 and NK3 receptors. Binding of Substance P to one receptor subtype or another will cause different chemical signaling to occur both inside and outside cells.

Homspera

Within a few years following the discovery of the amino acid sequence of Substance P, numerous synthetic analogues were being produced in an attempt to better understand how the structure and function of the molecule were related. One particular analogue was produced by replacing the amino acid glycine (Gly) with Sarcosine (Sar or N-methyl glycine) at the ninth position and the introduction of oxidized methionine (Met(O2)) in place of methionine (Met) at the eleventh position. The resulting peptide, still 11 amino acids long, but with a slightly higher molecular weight, was thus termed Sar9, Met (O2)11-Substance P. The amino acid sequence for this molecule, which we call Homspera, is presented below:

Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Sar-Leu-Met(O2)-NH2.

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These specific chemical alterations are presumably responsible for the different physiological actions of Homspera versus endogenous Substance P. In fact, Sar9, Met (O2)11-Substance P was first synthesized in an attempt to make chemicals that had specific distinctions in their activity from that of the parent Substance P molecule.

Homspera, or Sar9, Met (O2)11-Substance P, differs from Substance P in at least two ways. Homspera is reported to be active at only the NK1 receptor, and to be more resistant to the enzymes that break down Substance P, thereby terminating its action. Thus Sar9, Met (O2)11-Substance P is both more specific than Substance P, and less prone to degradation. These distinctions may provide the rationale by which Homspera's physiological effects differ from those of Substance P.

Product Development

Drug development in the United States is regulated by the United States Food and Drug Administration ("FDA").

The clinical development process begins with the submission of an Investigational New Drug Application ("IND") with the FDA. However, prior to filing an IND, information on the chemistry of the drug must be determined so that it can be produced in batches of known strength and purity. In addition, a number of animal studies are conducted to produce information on the pharmacology and toxicology of the drug. Lastly, detailed protocols for testing on human subjects must also be submitted along with that data.

Following the acceptance of an IND, the potential drug candidate is allowed to begin clinical study, which typically consists of three phases of development and takes approximately seven years. In Phase I, short-term clinical tests of the drug using healthy individuals are conducted to determine the drug's basic properties and safety profile in humans. Typically the drug remains in this stage for one to two years. Phase II phase consists of small-scale, longer-term tests for efficacy and safety. In phase II trials, dosage levels are experimented with to find optimal dosage levels, and further information on safety is collected. At the end of Phase II, the manufacturer meets with FDA officials to discuss the development process, continued human testing, any concerns the FDA may have, and the protocols for Phase III, which is usually the most extensive and most expensive part of drug development. In Phase III large-scale testing for safety and effectiveness is conducted. The primary information the FDA will use to decide whether the drug satisfies its benefit-risk relationship is developed in the Phase III trials. The trials are tightly controlled, may involve a large number of patients, and can take several months to several years for completion. The FDA may require, or companies may pursue, additional clinical trials, known as Phase IV clinical trials, after a product is approved. The results of Phase IV clinical trials can confirm the effectiveness of a drug and can provide important safety information to supplement the FDA's voluntary adverse drug reaction reporting system.

Once phase III is complete, the manufacturer files an NDA. Review of the NDA typically lasts one to two years, bringing total drug development and approval to approximately nine years. During the NDA stage, the FDA consults advisory committees made of experts to obtain a broader range of advice on drug safety, effectiveness, and labeling. In responding to a NDA, the FDA may grant marketing approval, request additional information or refuse to approve the application if it determines that the application does not provide an adequate basis for approval.

Product Pipeline

All our product candidates are in the pre-clinical stage of development. In May 2009, we submitted an Investigational New Drug (IND) application for the treatment of Idiopathic Pulmonary Fibrosis with the Food and Drug Administration (FDA). Following productive, detailed discussions with the FDA, the IND remains on clinical hold, which was the decision anticipated by Management based on known gaps in information required for the IND to be cleared by FDA. In addition, we have been issued two Pre-Investigational New Drug (PIND) numbers by the FDA, one for the treatment of avian influenza (PIND 73,709) and the other for the treatment of acute radiation

syndrome (PIND 63,255).

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The table below illustrates our current research and development-stage pipeline.

Product Candidate	Discovery	Pre-Clinical	Advanced Pre-Clinical	IND	Phase I	Phase II	Phase III
Idiopathic Pulmonary Fibrosis	X	X	X				
Influenza	X	X	X				
Neutropenia	X	X	X				
Vaccine Adjuvant	X	X					
Wound Healing	X	X					

The preliminary results of our pre-clinical studies using Homspera may not be indicative of results that will be obtained from subsequent studies or from more extensive trials. Furthermore, our pre-clinical or clinical trials may not be successful, and we may not be able to obtain the required regulatory approvals in a timely fashion, or at all. See "Risk Factors."

HOMSPERA®

In the early studies with the Air Force Office of Scientific Research, it was observed that the exposure of animals to JP-8 jet fuel resulted in pathological changes in the lungs and immune systems of those exposed. Homspera was administered to the test animals after prolonged exposure to the jet fuel. Based on the results of these studies, we believe that the administration of Homspera prevented some of the harmful effects of the jet fuel exposure in the lungs of the test animals, as well as had a positive effect on the animals' immune systems. However, there is no guarantee that our interpretation of the results of these studies will prove to be accurate after further testing.

Because of the results in other potential indications like radiation and infectious disease, which suggest a role for Homspera in stimulating the immune system, we are performing studies utilizing Homspera in applications with adult stem cells.

Pulmonary Fibrosis

Pulmonary fibrosis (PF) is a debilitating disease that gradually interferes with a person's ability to breathe. Pulmonary fibrosis belongs to a family of approximately 100 related diseases, called interstitial lung diseases, which have similar characteristics and can result in the fibrotic lung scarring that gives the disease its name.

Currently, our efforts are focused on the research and development of Homspera in the areas of pulmonary fibrosis (PF), influenza and radiation- (or chemotherapy-) induced neutropenia. One well known experimental model for pulmonary fibrosis involves the exposure of animals with enough radiation so that pulmonary fibrosis develops, generally within 6 to 9 months. The animals also show an increased susceptibility to pulmonary infections. We believe that in initial studies that Homspera have shown immunostimulatory activity in a number of animals and experimental conditions, including in multiple animal species exposed to influenza virus. Thus we believe that the radiation induction model for pulmonary fibrosis will allow us to examine Homspera's effect on radiation-induced neutropenia, as well as, the post-radiation pulmonary sensitization to viral infections in a single integrated experimental model.

Idiopathic Pulmonary Fibrosis

Sometimes pulmonary fibrosis can be linked to a particular cause, such as certain environmental exposures, chemotherapy or radiation therapy, residual infection, or autoimmune diseases such as scleroderma or rheumatoid

arthritis. However, in many instances, no known cause can be established. When this is the case, it is called idiopathic pulmonary fibrosis or IPF.

Idiopathic pulmonary fibrosis, or IPF, is the deadliest form of pulmonary fibrosis and is a progressive and ultimately fatal lung disease for which current therapy is minimally effective and the five-year survival rate is only 20%. However, several promising drugs are now in clinical trials, which may lead to significant improvements in prognoses. Further, it is possible, that a treatment for IPF will have broader applications in treating other forms of fibrosis affecting the liver, kidney, eye and skin, for example.

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Adult Stem Cells

Adult stem cells are undifferentiated cells that have the ability to differentiate and mature into more than one cell type. The ability of adult stem cells to become other cells can be limited to their position in the organism's body. For example, there are adult stem cells found in bone marrow that are blood-forming stem cells known as hematopoietic stem cells (HSC). Hematopoietic stem cells specifically form cells found in the blood: red blood cells, responsible for transporting oxygen and carbon dioxide; white blood cells, components of the immune system; and platelets that are involved in blood clotting.

Stem cells that are dividing or replicating are more sensitive to environmental hazards compared to cells that are in a resting state. During radiation and other toxic exposure, dividing stem cells can suffer damage to their DNA and propagate that damage to their daughter cells, rendering them useless. Resting stem cells are less prone to the mutations observed in dividing stem cells as they have more time to repair their DNA using built-in molecular repair systems.

We have conducted research to determine whether Homspera can trigger resting HSCs to proliferate, differentiate, and mobilize from bone marrow compartments to the peripheral circulation, thus replenishing damaged blood cells. Research has suggested that when Homspera is given to animals before exposure to radiation, white blood cell numbers significantly decrease and are similar to irradiated controls lacking the Homspera treatment; however, when Homspera is given to animals after radiation exposure, there is an increase in white blood cell numbers over time. Management hopes to determine whether the effects of Homspera on adult stem cells enable animals to regenerate their immune system by restoring white blood cells.

Studies were performed to evaluate the potential effects of Homspera in stimulating HSCs to differentiate into blood-cell precursors. Study findings showed that Homspera stimulated adult HSCs to differentiate into early-stage white blood cells (leukocytes). Homspera increased the number of early-stage white blood cells from controls and also produced this effect at low concentrations. Management believes these findings suggest Homspera's potential benefit in situations where regenerating or stimulating the immune system is desired, such as with patients undergoing chemotherapy or recovering from influenza or other infectious diseases.

We believe the results of previous influenza studies can be partly explained by Homspera's potential ability to enhance the immune system. In one study, Homspera treatment correlated with an increase in the survival of animals infected with influenza and co-treated with high dose Tamiflu® (Oseltamivir, Roche). Tamiflu (oseltamivir phosphate) is an oral anti-viral drug for the treatment of uncomplicated influenza and for the prevention of influenza in adults and children aged one year and older. Approved in over 80 countries, it is the centerpiece of many governments' plans for treating potential pandemic influenza. Additionally, there were decreased levels of virus in both the lungs and nasal passage in animals treated with Homspera. Also observed was an increase in antibodies when Homspera is administered as a vaccine adjuvant to an influenza vaccine in small animals. These results suggest a possible role for Homspera in stimulating the immune system to increase the numbers of white blood cells, thereby preparing or helping the body to identify and target invading micro-organisms or foreign particles.

Taken together, these results are consistent with our previous findings in areas such as radiation exposure, infectious diseases and vaccine adjuvant capability. The efficacy for these indications may be attributed, at least in part, to the potential ability of Homspera to stimulate adult hematopoietic stem cells, which become the cells of the immune system.

Wound Healing

The wound healing process is a complex, multi-faceted process typically defined by three distinct phases: inflammation, proliferation, and remodeling. Different cell types, ranging from structural cells in the skin such as fibroblasts and keratinocytes (that together play a major role in forming both the cellular structure as well as supporting collagen and keratin in skin) to cells of the immune system, are crucial for each stage of wound healing. We believe Homspera may have direct effects on a number of the cell types that are vital in each stage of the wound healing process. Additionally, we believe that Homspera's actions on adult stem cells may play a critical role in the wound healing process as well. Published literature regarding the role of Substance P, both endogenously-found and exogenously-applied, shows that it plays a role, via the NK1 receptor, in mobilizing adult stem cells from bone marrow and accelerating wound healing, thus suggesting that Homspera may be a wound healing therapeutic.

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In addition to cell culture studies, ImmuneRegen has sponsored an in vivo wound healing study using a porcine model of full-thickness, surgically-induced wound healing. Briefly, this study involved two Yorkshire pigs that were mechanically-wounded and each separate wound was treated immediately following wounding and every five days thereafter until the study's end with either Homspera or with a control only containing the solvent used to dissolve the Homspera. A full thickness wound involves the surface layer of skin (dermis) as well as the underlying tissue (epidermis).

The three phases of full thickness wound repair consist of: inflammatory, proliferative (sometimes called granulation), and remodeling. The inflammatory phase begins within minutes of the injury and lasts approximately 3 days. During this phase, blood vessels constrict and platelets gather to stop bleeding and form clots. The exudation of serum and white blood cells into damaged tissues results in localized redness, edema, and warmth. The proliferative phase begins with the appearance of new blood vessels and lasts from 3 to 24 days. During this phase, the vascular bed re-establishes, the area is filled with replacement granulation tissue, fibroblasts and collagen, wound contraction occurs, and the surface is repaired (epithelialization). The final stage of healing, the remodeling phase, may take more than a year depending on the depth and extent of the wound. During this phase, the collagen scar continues to reorganize and gain strength.

The studies indicated that the wounds receiving the highest dose of Homspera had healed more quickly. A reduction in wound size was observed over the time period of days 7-24 after the wound compared to controls, representing an acceleration of the proliferative (or granulation) phase of wound healing. Wounds treated with Homspera were observed in the study to close two days sooner (26 vs. 28 days) relative to controls in one of the treated animals and 1.5 days sooner (22.5 vs. 24) relative to controls in the other treated animal. Additional animal studies are being pursued to further elucidate the results observed in this experiment, as well as additional mechanistic information.

RADILEX®

All of our product candidates based on Radilex are in the pre-clinical stage of development. On January 14, 2004, we received a Pre-Investigational New Drug Application number for the use of Radilex (PIND No. 63,255) in the treatment of acute radiation syndrome.

Neutropenia

Neutropenia is a severe decrease of neutrophils, important infection-fighting white blood cells, in the blood stream. Neutrophils serve as the major defense of the body against acute bacterial and certain fungal infections. Without the key defense provided by neutrophils, a person has an increased risk of contracting bacterial infections, some of which can be life threatening. These infections are often difficult to diagnose, as patients lack the immune cells that drive the inflammation responsible for many of the symptoms of infection.

The most common causes of neutropenia are radiation or chemotherapy for cancer. Since these treatments are attempts to destroy the rapidly growing cancer cells, they tend to also injure the cells responsible for providing the blood with fresh red blood cells and white blood cells including the neutrophils, which the body consumes at the rate of approximately one trillion cells/day.

Some cancers affecting the cells in bone marrow are treated by high doses of drugs or radiation, which are intended to totally destroy the cancer cells. This often also destroys the bone marrow's ability to provide blood cells. This 'bone marrow ablation' would be lethal if the stem cells responsible for the continued replenishment of circulating blood cells couldn't be replaced. This is done by performing a bone marrow transplantation. Cells from one person's bone marrow are 'mobilized' into the circulation and harvested for future use, either in that same person, or one deemed a good 'match' for such a transplantation.

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We believe that available studies suggest Radilex may play a role in increasing an individual's ability to overcome the effects of radiation, and, in the cases of exposure to potentially lethal radiation, to play a role in increased rates of survivability. Based on the sum of these studies, we believe that a commercial market may develop for the potential use of Radilex as it relates to the treatment of radiation-induced side effects of cancer treatments, either as a stand-alone treatment or as a co-therapeutic agent to be used with other treatments. Further, we believe that Radilex, if developed, could be an acceptable candidate to be marketed to governmental agencies for national distribution in the event of a significant nuclear or radiological threat.

Further, excessive exposure to ionizing radiation over a short period of time leads to the development of radiation sickness, or Acute Radiation Syndrome (ARS). Exposure to lower doses of radiation may, either by accident or as a side effect of cancer treatment, result in the destruction of bone marrow cells responsible for maintaining the levels of red blood cells, white blood cells and platelets, resulting in compromised oxygen carrying capacity, diminished immune system function, and uncontrollable bleeding, respectively. More specifically, the blood-forming hematopoietic stem cells in the bone marrow compartment are the cells responsible for replacing damaged blood and immune cells.

Studies

To date we have sponsored and co-sponsored multiple studies utilizing rodents to examine the impact of Radilex treatment on survival, drug dose-dependent responses and the effects of different drug administration results. Acute total body irradiation exposure studies were performed at the University of Arizona Cancer Center, The Translational Drug Development (TD2) group from the Translational Genomics Research Institute (TGen) and at Oak Ridge National Laboratories (ORNL). We believe our study findings suggest Radilex may play a role in increased survival among tested rodents following exposure to lethal doses of ionizing radiation.

These studies showed that radiation damages the immune system, thereby contributing to death. We believe that the data from these radiation studies suggest Radilex shows efficacy in treating ARS by combating neutropenia. Neutropenia is a decrease in the levels of white blood cells in the blood and is a major medical condition associated with acute exposure to radiation and is also a side-effect of many chemotherapy agents. In exploring the potential mechanism for this result, we have identified an effect of Radilex on human adult stem cells and, more specifically, the hematopoietic, or blood-forming, stem cells. Because these cells are stem cells, they have the ability to self-renew or become specialized and functional cells through a maturation process. Hematopoietic stem cells can mature into red blood cells, white blood cells, or platelets, thereby providing a way to replace old or damaged cells. Therefore, hematopoietic stem cells replenish blood cells that are damaged in the circulation of animals exposed to radiation or cytotoxic chemotherapy. In irradiated animals, Homspera treatment increased the number of white blood cells, compared to control animals that were irradiated and not treated. Mechanistic cell culture studies have demonstrated that Homspera can stimulate the ability of hematopoietic stem cells to mature into early-stage white blood cells. Taken together these results lead us to believe that Homspera regenerates white blood cells in the circulation of animals exposed to radiation, and can play a pivotal role in the protective effect that we believe has been identified for Radilex.

We believe that a commercial market may exist for the use of Radilex as it relates to the treatment of radiation- or chemotherapy- induced side effects of cancer treatments, either as a stand-alone treatment or as a co-therapeutic agent to be used with other therapies. Further, we believe that Radilex, if developed, may be an acceptable candidate to be marketed to governmental agencies for procurement.

We believe these animal studies provide support for our continued effort to research and develop Radilex to treat the effects of exposure to radiation. However, there is no assurance that our interpretation of the results of the studies will prove to be accurate after further testing.

VIPROVEX®

All of our product candidates based on Viprovex are in the pre-clinical stage of development. We are researching the efficacy of Viprovex as a potential treatment, either as a stand-alone application or as co-therapeutic treatment, for exposure to various biological agents, such as infectious diseases, including influenza and anthrax. We are also researching the efficacy of Viprovex as a potential treatment for exposure to chemical agents.

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Screening studies have been performed at the National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIAID) at its Antimicrobial Acquisition and Coordinating Facility (AACF). We believe the screening studies suggest that any anti-viral effect observed in infected animals potentially reflected an impact of Viprovex on the host immune system rather than a direct antiviral effect.

We have examined the potential of Viprovex as a vaccine adjuvant, which is to be used with other drugs. A vaccine adjuvant improves the host's immunological response to the vaccine antigen(s), without causing the host to stimulate an immune response against it. In studies performed under our sponsorship, we believe we have identified a potential vaccine adjuvant capability of Viprovex in a study utilizing a protein-based vaccine for highly pathogenic influenza. In one study performed in rodents, results suggested an improved host immune response to the vaccine and improved survival in animals infected with lethal H5N1 influenza of the types currently identified as pre-pandemic risks in Asian bird populations and in humans. Additional animal studies have appear to corroborate this vaccine adjuvant activity of Viprovex, as results continued to suggest Viprovex enhances the host immune response to the vaccine administered in parallel with Viprovex.

Based on early studies on Homspera and existing literature on Substance P, we are also researching Viprovex as a potential treatment for exposure to chemical agents, such as formalin. Formalin, a highly toxic chemical that is used by the chemical industry, is a solution of formaldehyde gas dissolved in water. A preliminary study suggested an anti-inflammatory action of Viprovex in animals exposed to formalin vapor.

If Viprovex can be developed, we believe that potential commercial opportunities may exist for the treatment of seasonal influenza and other viral or bacterial infections, either as a stand-alone drug or in conjunction with other drugs. In addition, we believe that potential applications may exist for sale to governments for the treatment of exposure to anthrax and pandemic influenza – either as stand-alone treatments or as vaccine adjuvants.

Biological Exposure Applications

Infectious Disease - Seasonal and Pandemic Influenza

We believe that results from our studies may reveal the potential ability of Viprovex to enhance flu therapies, minimize the respiratory impact of influenza infection and augment the capability of vaccination to induce a protective immune response.

In October 2003, the Air Force Office of Scientific Research sponsored preliminary studies with the Hong Kong influenza virus (A/Hong Kong/8/68) and Viprovex at the University of Arizona, Arizona Health Sciences Center, Lung Injury Laboratory. We believe that these studies suggest that when mice were exposed to the irritant JP-8 jet fuel and then inoculated with the Hong Kong respiratory virus (HKV), they experienced elevated levels of inflammatory cells in their lungs. These levels were reduced in animals also treated with Viprovex. In contrast to control animals exposed to the virus, the JP-8 treated animals also treated with Viprovex did not develop the clinical symptoms of viral infection, which included increases in alveolar macrophages and neutrophils in broncho-alveolar lavage fluid.

Macrophages and neutrophils circulate in the blood and survey the body for foreign substances. When they find foreign antigens, such as viruses, they engulf and destroy them. Neutrophils are inflammatory cells and are the most common white blood cell type. Alveolar macrophages and neutrophils are components of the immune system that are expressed out of the blood and into the fluid inside the lungs coating the alveoli. The alveoli, found in the respiratory zone of the lungs, are primary sites of gas exchange where blood and air exchange oxygen and carbon dioxide carried by red blood cells. The fluid is acquired and assayed by lavage (washing the lung airways with liquid) and assessing the cells and chemicals in this wash fluid. Animals treated with Viprovex also exhibited lower levels of leukotriene B4 (LTB4), a chemical released by white blood cells during an immune response, than animals not treated with Viprovex.

Elevated LTB4 would attract the inflammatory cells, particularly neutrophils, which would follow infection with a virus. Electron micrographs showed healthier, normal appearing cells in the airways with no virus particles in the Viprovex-treated animals, in contrast to the HKV/JP-8 controls, suggesting, in our opinion, that Viprovex actually prevented viral replication and pathology, perhaps by stimulating the pulmonary alveolar macrophages to actively attack, engulf and destroy the virus more effectively. Without virus particles in the lungs, there would be no need to mount an immune response. Based on the results of this study, we believe that Viprovex may be potentially used to increase the ability of the body's own immune system to naturally fight off flu strains, thereby presenting the possibility that Viprovex could be used either as a stand- alone treatment or as an adjunct to a vaccine or other therapy.

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On November 29, 2005, we applied for a PIND from the Department of Health and Human Services (HHS) for the use of Viprovex in the treatment of avian influenza. The PIND number for the use of Viprovex in treating avian influenza was issued on December 19, 2005 (PIND No. 73,709).

Subsequently, we have sponsored influenza studies conducted at Virion Systems, Inc., utilizing rodents to test the efficacy of Viprovex in treating the human influenza A/Wuhan/359/95 (H3N2), a model system for studying respiratory viruses that infect humans. We believe results demonstrated that Viprovex attenuated the symptoms of influenza by decreasing weight loss and hypothermia and also decreased viral levels in lungs and nasal passages over non-treated, infected animals. In similar studies, animals were infected with H3N2 and treated with Viprovex, the anti-viral drug Tamiflu® (oseltamivir, Roche), or both. Pulmonary inflammation was assessed by a trained histopathologist and showed, in our belief, to be inhibited by Viprovex.

In our opinion, the data acquired to date examining the effect of Viprovex on influenza infection suggests an anti-viral action occurs in the lungs and, more noticeably, in the nose. Further, in conjunction with the suggested anti-viral effect, animal weights and temperatures were normalized. Differences in cytokines, small peptidesignaling molecules released by cells of the immune system to mediate inflammation and immune responses, were also witnessed. In the opinion of management, such Viprovex-induced changes in immune response as evidenced by cytokine signals demonstrate the potential efficacy of Viprovex. Based on our results, we believe that Viprovex may show efficacy as a stand-alone drug in the treatment of influenza. Further, when used in conjunction with a neuraminidase inhibitor, currently the most effective pharmacological agents (zanamivir (Relenza®, GlaxoSmithKline) and oseltamivir (Tamiflu®, Roche)) to treat influenza by inhibiting an enzyme necessary for infectivity, Viprovex might be an effective therapeutic adjuvant, treating or mitigating the pathology associated with influenza infection.

We have also performed studies in the laboratory of Dr. Theodore Ross, University of Pittsburgh. Dr. Ross is renowned for his research and development of effective vaccines for influenza, HIV-1, and emerging infectious diseases. He has extensive experience in evaluating immune response characteristics in preclinical models for various influenza and HIV vaccines, including virus-like particle (VLP)-based vaccines, and he has established animal models to assess both cellular and humoral immune responses to antigens. His most recent publications have evaluated the efficacy of an H5N1 VLP-based vaccine. In the studies performed for ImmuneRegen, Viprovex was tested in rodents and ferrets against the pandemic H1N1 influenza A virus as well as the H5N1 avian influenza virus. Results show that Viprovex can positively impact the severity and duration of viral infection and in cases where virus infection causes death, Viprovex can diminish lethality. This data adds further support to Management’s belief that Homspera can be developed as a standalone therapeutic against influenza virus infection by virtue of its immunomodulating activity.

There is no assurance that our interpretation of the results of the studies will prove to be accurate after further testing.

Vaccine Adjuvant

Vaccine adjuvants are chemicals, traditionally co-administered with vaccines, which are designed not to stimulate an immune response when administered on their own but, rather improve the immune response to other, co-administered antigens. Vaccine adjuvants are not antigens on their own. The first FDA-approved adjuvant was alum. Alum is the generic name for aluminum salts, generally aluminum hydroxide and aluminum phosphate, which were first used as adjuvants in 1926. New adjuvants generally consist of derivatives of nucleic acids or lipids that most typically would be found within invading micro-organisms, alone or in combination. These micro-organism derived chemicals trigger the host’s immune system to provide a more robust response, enhancing the host’s ability to fight off infection by the micro-organism.

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Results from studies in animals suggest that Viprovex may have potential value as a vaccine adjuvant.

Under a co-development agreement with GenPhar, Inc., Viprovex was evaluated for adjuvant activity in combination with GenPhar's pandemic influenza vaccines in a murine model of vaccination and virus challenge. In this model, mice were vaccinated with GenPhar's proprietary avian influenza vaccines against Spanish flu or avian flu and challenged by exposure to highly pathogenic Spanish or avian flu viruses at concentrations that ordinarily would be lethal to the mice. The Viprovex-adjuvanted vaccine resulted in an approximate 300% increase of influenza virus antibody levels in animals evaluated for Spanish-flu proteins and roughly a 50% increase in animals evaluated for Avian flu proteins. This adjuvant activity correlated with the animals' enhanced survival after intranasal challenge with highly pathogenic avian (H5N1) influenza, because while no unimmunized animals survived challenge, 33% of the Spanish flu-vaccinated animals survived challenge, while 100% of Spanish flu-vaccinated mice that received Viprovex survived.

Studies sponsored by us have also shown enhanced immune responses to antigens co-administered subcutaneously with Viprovex. This adjuvant activity on co-administration is the more typical route for currently administered adjuvants, which are included in vaccines and are administered with a single, usually intramuscular, injection. These findings suggest additional mechanisms may be invoked by Viprovex, perhaps including direct, receptor-mediated stimulation of the antigen-presenting cells of the immune system. A combination of increasing immune cell number and directly enhancing immune cell activity could underlie Viprovex's effectiveness as a vaccine adjuvant.

Additional studies conducted with Viprovex in cell culture have shown an increased immune response to vaccine components, as the vaccine adjuvant increased immune responses to vaccine components. Additionally, the anti-anthrax activity reported by Viprovex is similarly consistent with activation of components of innate immunity that have been reported to have anti-anthrax activity, such as defensins, small peptides found in immune cells that help destroy invading bacteria.

We believe that the potential efficacy of Viprovex as a vaccine adjuvant, as detailed above, likely results from the unique combination of two mechanisms through which Viprovex affects the immune system. As mentioned, the actions of Viprovex are mediated predominately through interactions with the neurokinin-1 receptor (NK1-R) which in turn stimulates stem and immune cell activity. We believe that these actions on stem cells and circulating immune cells may underlie the vaccine adjuvant capability.

Adjuvant activity using vaccination with cancer antigens: Melanoma mitigation

Studies performed by Dr. Adriana Larregina, MD, PhD, Associate Professor at the University of Pittsburgh, have evaluated the chemical that is Homspera and have published these results in the medical literature (referenced as Mathers AR et al., 2007 and Janelsins BM et al., 2008). Briefly, she has shown:

- Homspera prolongs immune cell (Dendritic cell) survival through NK1-R activation
- This prolonged survival is retained when exposed cells are returned into experimental animals

- Mechanisms of action are additive to other processes that utilize the NF-kB pathway, as does Homspera
- Activation by Homspera includes the generation of antigen-specific helper T-cells

Homspera increases the ability of genetic vaccines to produce their antigenic payload which stimulates the immune response to the vaccine

Homspera makes the activated Dendritic cells more effective at getting to the lymph nodes, makes the lymph nodes more receptive to the DCs, and increases the responsiveness of DC in the lymph nodes

Homspera increases the antibody response of the immune system as well as the release of cytokines that drive the immune response

The result of the multi-pronged immuno-stimulation by Homspera and antigen is a long-lasting immune response to the administered antigen

The prolonged targeted immune response results in an inhibition in the growth of cancer transferred into the treated animals.

There is no assurance that our interpretation of the results of the studies will prove to be accurate after further testing.

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Anthrax

Anthrax is an often-fatal human disease resulting from infection of the bacterium Bacillus anthracis. Anthrax is most often contracted by skin to skin, or cutaneous, contact with an infected lesion, resulting from the handling of infected animal products. Cutaneous anthrax has a mortality rate of roughly 20%. Inhalation of B. anthracis spores results in a severe and often-times lethal infection, with mortality rates of greater than 80%. As a result of the high mortality rate and broad route of infection, anthrax is considered a prominent agent of bioterrorism.

To date we have sponsored multiple anthrax studies, which were conducted utilizing rodents to evaluate the efficacy of Viprovex in reducing the mortality rate of an active pulmonary infection of anthrax. Results suggest that when treated with Viprovex prior to exposure to anthrax spores, Viprovex elicited protective, prophylactic efficacy. When treated a short time after exposure to anthrax spores, Viprovex elicited post-exposure, pre-symptom prophylactic efficacy.

We signed a Material Transfer Agreement with VaxGen, Inc. in August of 2007 with the intention of receiving the pharmaceutically active ingredient of VaxGen's anthrax vaccine candidate to be tested in combination with Viprovex. When VaxGen ceased actively developing this product (rPA102) in 2007, we began discussions with alternative manufacturers of anthrax vaccine candidates. We believe such materials can be acquired for testing with Viprovex although in light of ongoing studies and uncertainties in governmental procurement activities for an anthrax treatment, we have not made this a Company priority.

Further research, in our opinion, has supported these findings of prophylactic efficacy of Viprovex against anthrax and also demonstrated Viprovex to show efficacy in increasing survival rates in mice pretreated with anthrax. Additionally, while these results are preliminary, we believe that Viprovex could play an important role, in conjunction with other therapies, in improving treatments of anthrax exposure.

There is no assurance that our interpretation of the results of the studies will prove to be accurate after further testing.

Chemical Exposure Applications

Based on early studies on Homspera and JP-8 jet fuel and existing literature on Substance P, we have performed research on the efficacy of Viprovex as a potential treatment for exposure to chemical agents. To date, we have only conducted limited preclinical studies with regard to the development of Viprovex for indications related to treatment of exposure to harmful chemicals.

There is no assurance that our interpretation of the results of the studies will prove to be accurate after further testing.

JP-8 Jet Fuel and Smoke

We believe our early AFOSR rodent studies demonstrated the administration of Substance P and Homspera to animals exposed to JP-8 decreased the inhibiting effect of jet fuel inhalation on the immune system, while administration of antagonists to Substance P increased the inhibiting effect on the immune system. Further experiments performed using Viprovex examined Viprovex's effectiveness in preventing lung injury caused by inhalation of toxic diesel exhaust fumes. In our opinion based on our results, Viprovex has been shown to exhibit anti-inflammatory effects in animal models.

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Research and Development

Research partners have continued to provide research services to IRBS during the year ending December 31, 2010. Studies underway at academic, corporate and government laboratories within the US and abroad have provided, at no additional expense to ImmuneRegen, additional insights into Homspera activity and potential clinical utility. These activities continue unabated as they are stimulated by the interests of the outside investigators and funding of this work (except for the providing of Homspera) is provided by the investigators' institutions.

University of Rochester

Recent work performed by research groups under the direction of Dr. Jacob Finkelstein, professor in the departments of Pediatrics, Radiation Oncology and Environmental Medicine at the University of Rochester Medical School, Rochester, N.Y., has looked at the effect of Homspera to mitigate the acute and chronic impact of ionizing radiation and neonatal hyperoxemia on pulmonary structure and function. These results, while preliminary, will underpin ImmuneRegen's orphan product designation application for Homspera.

Dr. Finkelstein is a co-director at The University's Center for Biophysical Assessment and Risk Management Following Irradiation (CBARMFI), which exists to bring together the knowledge, technologies, and effort of a multidisciplinary, international team of scientific personnel in order to develop medical countermeasures to radiological terrorism. The Center housed at the University of Rochester is one of 8 NIH/NIAID funded centers throughout the United States. In August 2010, the National Institute of Health / National Institute of Allergy and Infectious Disease awarded the University of Rochester Medical Center (URMC), a $15 million five-year, continuation grant for studies that utilize ImmuneRegen's Homspera. This grant followed an initial grant of $21 million in 2005 to the University to become part of a national research network - the Centers for Medical Countermeasures Against Radiation.

National Cancer Institute, NIH

Based on initial findings of Homspera activity, researchers at the National Institute of Health (NIH) / National Cancer Institute (NCI) are evaluating Homspera's effect on mucosal immunity in an effort to further define the mechanisms that make Homspera an effective vaccine adjuvant.

Scancell

Scancell Holdings Plc, a UK based developer of therapeutic cancer vaccines, is performing follow-up studies designed to optimize the effects of Homspera in enhancing the next generation of Scancell's cancer vaccines.

Radboud University Nijmegen Medical Centre

Investigators have instituted studies looking at activity in new and innovative cancer vaccine paradigms using Homspera at the Nijmegen Centre for Molecular Life Sciences, Radboud University Nijmegen Medical Centre, a leading academic centre with expertise in medical science and healthcare in the Netherlands.

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Orphan Status for Treatment of Idiopathic Pulmonary Fibrosis

The Orphan Drug Act (ODA, signed into law January 1983) provides for granting special status to a product to treat a rare disease or condition. The drug's sponsor demonstrates by submission of certain designated information to FDA that the product may be able to treat the rare disease or condition. Upon review, if subsequent orphan designation is granted by FDA, the sponsor of the product qualifies for the research and development tax credit and marketing incentives of the ODA. Additionally, a marketing application for a prescription drug product (for the designated disease or condition) that has been so designated ("orphan status") is not subject to a prescription drug user fee.

Per the ODA, in January 2010 ImmuneRegen submitted an application to the Office of Orphan Drug Products for Homspera as a treatment for idiopathic pulmonary fibrosis (IPF). The information submitted enabled FDA to grant orphan status to Homspera to treat IPF on March 13, 2011.

This determination means that a division within FDA has analyzed the data ImmuneRegen submitted regarding Homspera's impact in what they consider a valid animal model for IPF and agreed that the animal data and accompanying discussion supported the determination that Homspera might be of value in treating IPF.

Note that the approval of an orphan designation request does not alter the standard regulatory requirements and process for obtaining marketing approval; that is, safety and efficacy of a compound must be established through adequate and well-controlled clinical studies.

DEVELOPMENT PROGRAM

Research and Development Spending

Due to our liquidity and limited cash available our spending on research and development activities in the years ended December 31, 2010 and 2009 was limited. We spent approximately $269,041 and $558,923 in 2010 and 2009, respectively, in research and development activities related to the development of Radilex and Viprovex. From our inception in October 2002 until December 31, 2010, we have spent $3,687,860 in research and development activities. These costs only include the manufacture and delivery of our drug by third party manufacturers and payments to contract research organizations and consultants for consulting related to our studies and costs of performing such studies.

If we receive additional funds through investment funding, licensing agreements or grants we anticipate that during the next 12 months we will increase our research and development spending to a total of approximately $1,500,000 in an effort to further develop Radilex and Viprovex. This research and development cost estimate includes additional animal pharmacology studies, formulation and animal safety/toxicity studies.

We believe that initial revenues, if any, will likely be generated through partnerships, alliances and/or licensing agreements with pharmaceutical or biotechnology companies. Our focus during the next 12 months will be to identify those companies which we believe may have an interest in our proposed products and attempt to negotiate arrangements for potential partnerships, alliances and/or licensing arrangements. Alliances between pharmaceutical and biotechnology companies can take a variety of organizational forms and involve many different payment structures such as upfront payments, milestone payments, equity injections and royalty payments. To date, we have not entered into discussions with and have no agreements or arrangements with any such companies. Even if we are successful in entering into such a partnership or alliance or licensing our technology, we anticipate that the earliest we may begin to generate revenues from operations would be calendar 2010. There is no assurance that we will ever be successful in reaching such agreements or ever generate revenues from operations.

We will need to generate significant revenues from product sales and or related royalties and license agreements to achieve and maintain profitability. Through December 31, 2010, we had no revenues from any product sales, royalties or licensing fees. We have not achieved profitability on a quarterly or annual basis. Our ability to achieve profitability depends upon, among other things, our ability to develop products, obtain regulatory approval for products under development and enter into agreements for product development, manufacturing and commercialization. Moreover, we may never achieve significant revenues or profitable operations from the sale of any of our potential products or technologies.

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If product development or approval does not occur as scheduled, our time to reach market will be lengthened and our costs will substantially increase. Additionally, we may be requested to expand our findings to gather additional data or we may not achieve the desired results. If so, we may have to design new protocols and conduct additional studies. This will increase our costs and delay the time to market for our potential products, if any. Any of these occurrences would have a material negative impact on our business and our liquidity as it may cause us to seek additional capital sooner than expected and allow our competitors to successfully enter the market ahead of us.

If we are successful in achieving desirable results for these applications, we intend to design the protocols and begin further studies for this and other applications, when capital is available. As we have only collected preliminary data and additional studies are required, we cannot predict when, if ever, a viable treatments for these indications can be commercialized. If we do not observe significant results or we lack the capital to further the development, we may abandon such research and development efforts; thereby limiting our future potential revenues.

If we are successful in completing our studies and the results are as we anticipate, we intend to prepare and submit the necessary documentation to the FDA and other regulatory agencies for approval. If approval for Homspera, Radilex and/or Viprovex is granted, we expect to begin efforts to commercialize our product, if any, immediately thereafter, however, since we are currently in the pre-clinical stage of development, it will take an indeterminate amount of time in development before we have a marketable drug, if ever.

Grants

From time to time, we may apply for governmental grants and respond to formal requests from the government for additional information, thereby possibly allowing us to be included as a candidate for potential future grants.

Since our incorporation in October 2002, we have made submissions for twelve grants either by submitting Requests For Information (RFI), Requests for Proposal (RFP), Broad Agency Announcements (BAA), requests for white papers and/or fully executed grant applications. To date our applications for grant funding have not been accepted. We intend to continue to apply for grants; however, there can be no assurance that we will ever receive any grants.

Study Partners

Extensive time and money is required to be spent to develop new drug applications by the time they are approved by regulatory agencies for use on the market. In order to efficiently and expeditiously navigate the research, development and regulatory approval process in hopes of bringing our applications to market, our development program relies on the use of study partners and co-development relationships.

Contract Research Organizations (CRO's) are independent laboratories or other facilities that provide contract services to the pharmaceutical industry. These CRO's offer broad therapeutic expertise, advanced technologies and extensive resources for drug discovery and drug and device development, and in some instances partnering opportunities. In the opinion of management, using these outside organizations helps to maximize our flexibility and minimize our one-time costs in outsourcing very expensive programs to those companies that maintain the necessary infrastructure to perform these cost-effectively according to internationally recognized standards. Further, as product demands change, we believe that this structure will allow us to move our resources to more appropriate contract research or development or formulation or manufacturing facilities without incurring loss of time or money on outdated projects and programs. As we move our candidate products into FDA-compliant animal safety testing, we expect to contract with specialty groups, organizations or companies that meet regulatory requirements and have adequate and appropriate technical capabilities, rather than develop and maintain an animal use and care facility ourselves that is compliant with current Good Laboratory Practices.

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To date we have worked with numerous study partners and contractors including CRO's, biotechnology companies, hospitals, institutions and universities. Some of these partners and contractors include Celgene Corporation, HemoGenix, Inc., National Institutes of Health, Lovelace Respiratory Research Institute, University of California at Berkeley, University of Medicine & Dentistry of New Jersey, Pacific Northwest National Laboratory, Armed Forces Institute of Pathology, Southern Research Institute, Dynport Vaccine Company, Virion Systems, Hyperion Biotechnology, Charles River Laboratories, Apptec, TGA Sciences, BioQuant, The Children's Hospital of Philadelphia, AAI Pharma, CS Bio Company, Stemcell Technologies, Tandem Labs, University of Arizona, Integrated Biomolecule Corporation, Johns Hopkins Medicine, InvivoGen, MIR Preclinical Services, Covance, BioCure, MDx Bioanalytical, ULURU, DelSite Biotechnologies, Nelson Laboratories, U.K. Health Protection Agency, CARE, Dow Pharmaceutical Sciences, GE Healthcare, VaxDesign, Mayo Clinic, IITRI, MD Biosciences, Epitomics, GenPhar, University of Texas Southwestern, and the Translational Genomics Research Institute (TGen) Center for Translational Drug Development (TD2).

Advisory Boards and Consultants

As a virtual drug development company, we contract outside consultants related to the research and development, including quality and regulatory affairs, of our potential products and enlist the aid of advisory boards to provide additional insights.

Consultants

We currently contract four outside consultants related to the research and development, including quality assurance and regulatory affairs, of our potential products.

Dr. Joy A. Cavagnaro, Ph.D., DABT, RAC. Dr. Cavagnaro is is the President of Access BIO, Boyce, VA, a consultancy specializing in science-based regulatory strategies and preclinical product development services to facilitate biomedical research and emerging technologies. Specific product areas of expertise include vaccines, cellular and gene therapies, animal-based and plant-based biotherapeutics, biotechnology-derived and tissue engineered products. She has over 25 years experience in biotech spanning academia, the CRO and biotech industries and government, including the FDA. During her tenure at the FDA Center for Biologics Evaluation and Research Dr. Cavagnaro was appointed to the Senior Biomedical Research Service, served as FDA's topic lead for safety for the ICH initiative for 7 years. Dr. Cavagnaro’s engagement with us began on February 25, 2008 and is to provide expertise in support of our preclinical strategy regarding our drug development program. She is paid an hourly fee in cash.

Dr. Chet Leach, Ph.D. Dr. Leach was previously Director of Preclinical Toxicology for Lovelace and Director of Life Science Research and Development at Nektar Therapeutics, will serve as an independent consultant to us, assisting in planning upcoming clinical trials and non- clinical studies, and helping to prepare for eventual clinical trials of Homspera. Leach has nearly 30 years experience in toxicology and pulmonary drug development, having also held positions at IIT Research Institute, Battelle Pacific Northwest Laboratories, and 3M Pharmaceuticals, where he was head of Preclinical Pulmonary Drug Development. Dr. Leach‘s engagement with us began on February 14, 2008 and calls for him to assist in planning non clinical studies and to help prepare for eventual clinical trials of Homspera. He is paid an hourly fee in cash.

Dr. Pranela Rameshwar, Ph.D. Dr. Rameshwar is a professor at The University of Medicine and Dentistry of New Jersey, where she teaches and conducts translational research at the Medicine Department, Division of Hematology/Oncology. She received her undergraduate degree in Medical Microbiology from the University of Wisconsin, and her Ph.D. in Biology from Rutgers University, writing her doctoral thesis on the stimulatory effect of substance P on the immune system. Dr. Rameshwar has written over 100 articles on regenerative medicine, genetics,

and stem cell research and has presented over 140 abstracts at national and international meetings including the American Society of Hematology, the American Society of Immunologists, and the American Association for Cancer Research. She began consulting for us in December of 2007 and is paid a cash fee on an hourly basis for consulting on the design of study protocols and issues relating to Homspera's properties in comparison to endogenous Substance P.

Dr. Donna Hartzfeld, Ph.D., Founder, Quality Implementation Services, Inc. Quality Implementation Services, Inc. has designed proactive strategies to assist companies in reaching successful regulatory milestones in their drug and device approval process. Dr. Hartzfeld has over 18 years of Quality and Laboratory compliance experience in pharmaceutical, medical device, biotech, combination products, biologics and dietary supplements industries. She has launched a small pharmaceutical cGMP manufacturing facility, incorporating a comprehensive quality management infrastructure and built a fully functional analytical quality control laboratory. The facility successfully passed its first Pre-Approval Inspection (PAI) in less than four years from conception with no FDA observations. She has academic teaching experience at the university level and has applied her academic teaching skills to industrial training and to the development of innovative, educational materials to accompany inter-active training sessions. She currently serves on the Advisory Board of a life science project and document software management company in Phoenix, Arizona, and has been a member of various professional associations such as the Regulatory Affairs Professional Society, the Drug Information Association, the American Society for Quality and the Society of Quality Assurance.

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Advisory Boards

We currently have two advisory boards - the Scientific Advisory Board and the Bioterrorism Preparedness Advisory Board. Advisory board members are appointed for one-year terms by our management. For services rendered, members of our advisory boards are compensated on a quarterly basis in common stock purchase options issued under our 2003 Stock Option, Deferred Stock and Restricted Stock Plan.

The Scientific Advisory Board was formed to educate and provide direction with regard to the discovery, research and development of applications using Homspera in the areas of expertise of the various advisory board members. The following individuals comprise our Scientific Advisory Board:

Dr. John Dann, M.D., D.D.S. graduate of Harvard University Dental School and Washington University Medical School, Board Certified maxillofacial and cranial facial surgeon.

Dr. Jeffery Friedman, M.D., Diplomat, American Board of Cosmetic Surgery, American Board of Otolaryngology Head and Neck Surgery, Fellow of the American Academy of Cosmetic Surgery.

Dr. Susan E. Leeman, Ph.D, Professor in the Department of Pharmacology and Experimental Therapeutics at the Boston University School of Medicine. Dr. Leeman was one of the first scientists to isolate substance P in the central nervous and gastrointestinal systems. Dr. Leeman was elected to the National Academy of Sciences in 1991.

Dr. K.A. Kelly McQueen, M.D., MPH. Anesthesiologist and Public Health Consultant; Infectious Disease and Disaster Planning for U.S. Army and US Northern Combatant Command.

Dr. Pranela Rameshwar, Ph.D., Professor in the Department of Medicine, Division of Hematology/Oncology at the University of Medicine and Dentistry of New Jersey; research areas include Substance P, stem cells and cancer.

Dr. Ivan Rich, Ph.D., CEO and founder of HemoGenix, a biotechnology company focused on the development of 21st century stem cell assays.

The Bioterrorism Preparedness Advisory Board was formed to discuss logistics and coordinate between agencies and their first responder groups in the event of an attack or outbreak. We have attempted to appoint knowledgeable military and private citizens that possess first hand experience in combat casualty and mass trauma scenarios, including preparation for a bioterrorist attack and/or medical or scientific expertise. The following individuals comprise our Bioterrorism Preparedness Advisory Board:

Dennis E. Amundson, D.O., Captain, United States Navy, Medical Corps, Naval Medical Center, San Diego, Pulmonary Medicine.

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Frederick M. Burkle, Jr., M.D., Director, Asia-Pacific Center for Biosecurity, Disaster & Conflict Research, and a Professor in Tropical Medicine, Public Health and Epidemiology, at the University of Hawaii's John A. Burns School of Medicine, Senior Fellow, the Harvard Humanitarian Initiative and Director of the Asia-Pacific Branch and Senior Scholar, Scientist, and Visiting Professor at John Hopkins University Medical Institutes' Center for Refugee & Disaster Response.

Mr. Michael Caridi, Chairman, MAJIC Development Group, SRC Industries Inc. and Protection Plus Security Consultants, Inc.

Paul Carlton, M.D., Lt. General, USAF, Medical Corps, (Ret.), Director, Homeland Security for The Health Science Center The Texas A&M University System, Former USAF Surgeon General

William Hoehn, Ph.D., Visiting Professor, Georgia Tech, Sam Nunn School of International Affairs, Center for International Strategy, Technology, and Policy

Dr. Adriana Larregina, M.D. Ph.D., a University of Pittsburgh School of Medicine faculty member of the Dermatology and Immunology departments and director of the school's Cutaneous Biology Laboratories and Education. She has published extensively on the role dendritic cells and their precursors play in stimulating immune responses. Further, she has utilized the active component of ImmuneRegen's stem cell-active drug candidate, Homspera, in her published studies of dendritic cells and immune system activation. Over the past 15 years, Dr. Larregina has pioneered studies exploring the role of dendritic cells in the human immune system and has published numerous peer-reviewed manuscripts, invited reviews and book chapters in this field. She spent the early part of her career studying and practicing pathology in her native Buenos Aires, Argentina, prior to moving to the United States in 1998. Her industry-related memberships include the Society for Investigative Dermatology and the American Association of Immunologists. Dr. Larregina holds an M.D. from the National University of La Plata School of Medicine in Buenos Aires, and a Ph.D. in Immunology from the University of Buenos Aires School of Medicine.

Col. Kerrie Lindberg (Ret.), Colonel, USAF, Nurse Corps, (Ret.), Former Director, Defense Institute for Medical Operations (DIMO), Brooks City-Base, Texas

K.A. Kelly McQueen, M.D., MPH. Anesthesiologist and Public Health Consultant; Infectious Disease and Disaster Planning for U.S. Army and US Northern Combatant Command

Jacob Finkelstein, Ph.D., a professor in the departments of Pediatrics, Radiation Oncology and Environmental Medicine at the University of Rochester Medical School, Rochester, N.Y., renowned for his investigation into radiation's effect on the human pulmonary System, is a new member of our advisory board.

Dr. Finkelstein's broad experience as a project leader at the University's Center for Biophysical Assessment and Risk Management Following Irradiation (CBARMFI) is expected to help advance ImmuneRegen's development of its drug candidate, Homspera®, by conducting research to evaluate the adult stem cell-active compound'sability to mitigate the effects of otherwise lethal radiation exposure in animals. The CBARMFI is one of eight Centers for Medical Countermeasures Against Radiation (CMCR) funded by the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health. The initial ImmuneRegen-CBARMFI relationship will include support of research efforts and co-development funding of a mutually beneficial research strategy.

Dr. Finkelstein's laboratory studies the mechanisms of pulmonary injury to physiological, toxicological and radiological stimuli and specifically the role of the alveolar epithelium, the cells that line the airways in the lungs. These studies include examination of inflammatory processes and the roles of cytokines in the regulation of cells in

the lungs and the immune system. Additionally, investigators at CBARMFI have identified a number of compounds that can mitigate the deleterious effects of radiation and other environmental toxins on pulmonary function.

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Of particular interest to both ImmuneRegen and Dr. Finkelstein's laboratory are the mechanisms by which exposure to sufficient doses of radiation triggers pulmonary fibrosis, a debilitating and potential lethal long-term effect. Dr. Finkelstein's laboratory has shown the involvement of pulmonary epithelial cells and fibroblasts in post-radiation fibrosis, specifically in the growth and regulation of connective tissues in the lung. These are the same cell types that ImmuneRegen's Homspera has been shown to affect, as enhanced cell and connective tissue proliferation and appropriate developmental growth signals accelerate wound healing.

Dr. Finkelstein has presented his research at numerous international conferences and has been published in peer-reviewed journals, textbooks and technical reports. He has served as a grant-reviewer for a number of prominent associations, including the American Lung Association and the Veteran's Administration, and serves on the editorial boards of many scientific journals. His industry-related memberships include the American Association for the Advancement of Science, the American Chemical Society (Division of Biological Chemistry) and the American Society for Biochemistry and Molecular Biology, among others. Dr. Finkelstein holds a Ph.D. in Biochemistry from Northwestern University and a bachelor's degree in chemistry from Carnegie-Mellon University.

MANUFACTURING

As previously discussed, we expect that Homspera, Radilex and Viprovex will ultimately have distinct formulations and dosing regimens, however, at this early stage of development, the formulations used are identical. We do not have, and do not intend to establish, manufacturing facilities to produce Homspera, Radilex or Viprovex or any other potential products, if any, that may be derived from Homspera.

In September 2009, ImmuneRegen announced an agreement with Bachem, Inc., enabling Bachem to be the primary manufacturer of ImmuneRegen's Homspera drug substance. Under the agreement Bachem will produce the active pharmaceutical ingredient Homspera under current Good Manufacturing Practices (cGMP) in quantities necessary to support formulation, pre-clinical studies and to perform a number of Phase I studies in humans under an FDA-cleared Investigation New Drug Application (IND). Only drugs produced under cGMP may be administered to humans. Bachem is an independent, technology-based, public biochemicals company providing full service to the pharma and biotech industry. Bachem is specialized in the process development and the manufacturing of peptides and complex organic molecules as active pharmaceutical ingredients (APIs), as well as innovative biochemicals for research purposes. With headquarters in Bubendorf, Switzerland, and affiliates in Europe and the US, Bachem works on a global scale and holds a leading position in the field of peptides.

The manufacture of Homspera, Radilex, Viprovex or any potential products, if any, derived from Homspera, whether done by outside contractors, as planned, or internally, will be subject to rigorous regulations, including the need to comply with the FDA's current Good Manufacturing Practice (cGMP) standards. As part of obtaining FDA approval for each product, each of the manufacturing facilities must be inspected, approved by and registered with the FDA. In addition to obtaining FDA approval of the prospective manufacturer's quality control and manufacturing procedures, domestic and foreign manufacturing facilities are subject to periodic inspection by the FDA and/or foreign regulatory authorities.

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PATENTS AND PROPRIETARY RIGHTS

We are developing Substance P analogues for a variety of uses. Our intellectual and proprietary rights with respect to these developments are essential to our business. We file patent applications to protect our inventions, and improvements to our inventions that we consider important to the development of our business. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

We have filed patent applications directed to various methods of using and compositions comprising Substance P analogues. As of December 31, 2010 we owned approximately fourteen issued patents, including three issued U.S. patents and eleven issued foreign patents. Also as of December 31, 2010 we had approximately twenty-three pending patent applications and twelve filed and waiting for review. All inventions embodied in these applications and issued patents have been assigned to the company by the inventors. In addition, we have entered into a license agreement with the University of Pittsburgh whereby we have licensed the University's ownership interest to a patent that was jointly filed with the University of Pittsburgh.

We currently own issued patents in the U.S. drawn to methods of using one or more Substance P analogues to inhibit metastasis and to stimulate the immune system of immunocompromised individuals. Similar patents have been issued in Europe and Australia. We were also granted a patent in Singapore for the use of Substance P analogues to ameliorate the effects of cigarette smoke.

We have also filed U.S. and foreign patent applications for a variety of uses of the substance P analogues including treating infectious diseases, pulmonary disorders, hematologic disorders, wound healing, as well as various uses in the areas of stem cell technology, dermatology and cosmetics. Because these applications have not yet been granted, the rights in these subject matters remain potential.

Some of our research has been funded by the Air Force Office of Scientific Research and has been conducted at the University of Arizona. We have received waivers of ownership rights from the United States Air Force and the University of Arizona in regard to issued U.S. Patents 5,945,508 and 5,998,376 and pending patent applications in this family. We are expecting to receive similar waivers from the United States Air Force and the University of Arizona for any remaining patent applications that may be subject to such rights.

Although we own U.S. Patent Numbers 5,945,508 and 5,998,376, (Substance P Treatment for Immunostimulation), our rights in those patents are subject to certain limitations with respect to the University of Arizona and the United States Air Force as described below. If patents are issued for any of our pending patent applications in this patent family, the same limitations would most likely apply.

Our agreements with the University of Arizona outline specific rights in regard to our sponsored-supported projects. In accordance with our sponsored-supported project agreements, the University of Arizona retains the right to use data developed during these projects for non-commercial purposes, including teaching, research and education. ImmuneRegen BioSciences, Inc. retains the rights to trade secrets, inventions, developments and discoveries as limited by the University of Arizona's employment contracts in effect at the time the intellectual property was created. Further to this point, the principal investigator at the University of Arizona, Dr. Mark Witten, was a consultant to ImmuneRegen BioSciences, and, under the terms of his consulting agreement, ImmuneRegen BioSciences, Inc. retains rights to any developments or discoveries that he made in the course of working for us.

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As a result of governmental funding, the U.S. Government has certain rights in the technology developed with such funds. These rights include a non-exclusive, paid-up, worldwide license for any governmental purpose. In addition, the government has the right to require us to grant an exclusive license to any such funded invention to a third party if the government determines that: (i) adequate steps have not been taken to commercialize such inventions, (ii) such action is necessary to meet public health or safety needs, or (iii) such action is necessary to meet requirements for public use under federal regulations.

In this regard, the United States Air Force has reserved a non-exclusive license to U.S. Patent Number 5,945,508 and 5,998,376 in connection with Air Force grant F49620-94-1-0297 and may, under certain conditions, have commensurate or additional license rights under the Bayh-Dole Act. Those rights are set forth in 35 U.S.C. §202(c)(4) and 37 C.F.R. §§401.9 and 14(a).

Under the federal Bayh Dole Act, a party which acquires an exclusive license for an invention that was partially funded by a federal research grant is subject to the following government rights: (i) products using the invention which are sold in the U.S. are to be manufactured substantially in the U.S. unless a waiver is obtained; (ii) the government may force the granting of a license to a third party who will make and sell the needed product if the licensee does not pursue reasonable commercialization of a needed product using the invention; and (iii) the U.S. Government may use the invention for its own needs.

Besides the rights that have been granted to the U.S. Government, the validity and breadth of claims in medical technology patents involve complex legal and factual questions and, therefore, may be highly uncertain. No assurance can be given that any patents based on pending patent applications or any future patent applications by us will be issued, that the scope of any patent protection will exclude competitors or provide competitive advantages to us, that any of the patents that have been or may be issued to us will be held valid if subsequently challenged or that others will not claim rights in or ownership of the patents and other proprietary rights held by us. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of our products or design around any patents that have been or may be issued to us. We also cannot be certain that others did not first file applications for inventions covered by our pending patent applications, nor can we be certain that we will not infringe any patents that may be issued to others on such applications.

We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements. It is our policy to require our employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific limited circumstances. We also require signed confidentiality or material transfer agreements from any company that is to receive our confidential information. In the case of employees, consultants and contractors, the agreements generally provide that all inventions conceived by the individual while rendering services to us shall be assigned to us as our exclusive property. There can be no assurance, however, that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets or unpatentable know-how will not otherwise become known or be independently developed by competitors.

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Our potential success will also depend in part on our ability to develop commercially viable products without infringing the proprietary rights of others. We have conducted preliminary freedom to operate inquiries on four potential uses of substance P analogues: (i) treatment or prevention of avian influenza in mammals; (ii) wound healing stimulation, especially in irradiated persons; (iii) enhancing a response to a vaccine; and (iv) immunostimulation of immunocompromised individuals. These searches were limited to claim scope and did not address validity issues. Although the inquiry did not uncover any claims which would impede our freedom to operate, no assurance can be given that patents do not exist or could not be filed which would have an adverse affect on our ability to market our technology or maintain our competitive position with respect to our technology. If our technology components, devices, designs, products, processes or other subject matter are claimed under other existing U.S. or foreign patents, or are otherwise protected by third party proprietary rights, we may be subject to infringement actions. In such event, we may challenge the validity of such patents or other proprietary rights or we may be required to obtain licenses from such companies in order to develop, manufacture or market our products. There can be no assurances that we would be able to obtain such licenses or that such licenses, if available, could be obtained on commercially reasonable terms. Furthermore, the failure to either develop a commercially viable alternative or obtain such licenses could result in delays in marketing our proposed technology or the inability to proceed with the development, manufacture or sale of products requiring such licenses, which could have a material adverse affect on our business, financial condition and results of operations. If we are required to defend ourselves against charges of patent infringement or to protect our proprietary rights against third parties, substantial costs will be incurred regardless of whether we are successful. Such proceedings are typically protracted with no certainty of success. An adverse outcome could subject us to significant liabilities to third parties and force us to curtail or cease our development and sale of our products and processes.

We may collaborate in the future with other entities on research, development and commercialization activities. Disputes may arise about inventorship and corresponding rights in know-how and inventions resulting from the joint creation or use of intellectual property by us and our collaborators, partners, licensors and consultants. As a result, we may not be able to maintain our proprietary position.

Trademarks

On August 15, 2006, Viprovex became our federally registered trademark (Registration Number 3,130,407) in International Class 5 with respect to pharmaceutical products, namely antidotes for the treatment of viral, chemical and biological warfare agents.

On October 30, 2007, Radilex became our federally registered trademark (Registration Number 3,325,241) in International Class 5 with respect to biotechnology pharmaceuticals, namely, products for counteracting exposure to radiation and chemical agents.

On November 6, 2007, ImmuneRegen became our federally registered trademark (Registration Number. 3,329,995) in International Class 5 with respect to biotechnology pharmaceuticals, namely adjuvants, counter-actants and immunostimulant products for enhancing the natural and reactive immunity to toxic agents.

On April 15, 2008, Homspera became our federally registered trademark (Registration Number 3,411,933) in International Class 5 with respect to biotechnology pharmaceuticals, namely adjuvants, counter-actants and immunostimulant products for enhancing the natural and reactive immunity to toxic agents.

RESEARCH AND LICENSE AGREEMENTS

Our patents and continued research on Sar9, Met (O2)11-Substance P are derived from discoveries made during research studies funded by the Air Force Office of Scientific Research in 1994 by our co-founders Drs. Mark Witten

and David Harris. In December 2002 we entered into consulting agreements on a month-to-month basis with Dr. Mark Witten and Dr. David Harris. Under the terms of these agreements, Drs. Witten and Harris agreed to place at the disposal of us their judgment and expertise in the area of acute lung injury. In consideration for these services, we agreed to pay each of Drs. Witten and Harris a non-refundable fee of $5,000 per month. We and Dr. Harris agreed to terminate the consulting agreement for Dr. Harris in March 2005. In January 2006, the company received correspondence from Dr. Witten stating that he would terminate his consulting contract if his specific requirements were not met. We subsequently accepted his termination effective February 1, 2006.

In December 2002, we entered into a royalty-free license agreement with Drs. Witten and Harris. Under the terms of the license agreement, Drs. Harris and Witten granted to us an exclusive license to use and sublicense certain patents, medical applications, and other technologies developed by them. Our obligations under this agreement include (i) reasonable efforts to protect any licensed patents or other associated property rights; (ii) reasonable efforts to maintain confidentiality of any proprietary information; (iii) upon the granting by the U. S. Food and Drug Administration to us the right to market a product, we will, for so long as we sell any product or medical application which incorporates or utilizes the patents, medical applications, and other technologies developed by Drs. Witten and Harris, maintain in full force and effect policies of general liability insurance (with Broad Form General Liability and Product Liability endorsements) with limits of not less than $1,000,000 per occurrence and $1,000,000 annual aggregate. The license agreement will terminate ten years after the date of the expiration of the last patent issued or issuing with respect to the licensed patents, medical applications, and other technologies. The resignation of Dr. Harris as a director of our company in December 2004 and as a consultant in March 2005 does not have any impact upon the terms of the license agreement. The resignation of Dr. Witten as a consultant to our company in February 2006 does not have any impact upon the terms of the license agreement.

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In February 2005, Drs. Witten and Harris executed assignment documents in which, for good and valuable consideration, patent applications and patents developed by them were assigned to ImmuneRegen BioSciences, Inc. The assignment documents included all of the patents and patent applications which were included in and covered by the Licensing Agreement, as amended. Drs. Witten and Harris have also assigned all proprietary technology developed at ImmuneRegen subsequent to the execution of the February 2005 assignment documents.

All patent applications filed subsequent to those assigned by Drs. Witten and Harris have been assigned to ImmuneRegen by the inventors.

Studies using Homspera were performed in the laboratories of Dr. Adriana Larregina, M.D., Ph.D., currently Associate Professor in the departments of Dermatology and Immunology, University of Pittsburgh School of Medicine, and ImmuneRegen and the University have negotiated a license agreement that supports ImmuneRegen's vaccine development program. In this license, ImmuneRegen obtains rights to use Dr. Larregina's research data as well as a license to the University's ownership interest in a patent recently filed by ImmuneRegen in support of Homspera's intellectual property portfolio.

COMPETITION

The biotechnology and pharmaceutical industries are intensely competitive. We have numerous competitors in the United States and elsewhere. Because we are pursuing potentially large markets, our competitors include major multinational pharmaceutical companies, specialized biotechnology firms and universities and other research institutions. Several of these entities have already successfully marketed and commercialized products that will compete with our products, assuming that our products gain regulatory approval. Competitors such as Amgen Inc. and Cleveland Biolabs, Inc. have developed or are developing products for treating aspects of severe acute radiation injury. Companies such as PharmAthene, Inc. and Emergent BioSolutions, Inc. have developed or are developing vaccines against infectious diseases, including anthrax. Companies like InterMune Pharmaceuticals and Actelion Pharmaceuticals Ltd. are developing products for treating idiopathic pulmonary fibrosis.

Many of our competitors have greater financial and other resources, larger research and development staffs and more effective marketing and manufacturing organizations than we do. In addition, academic and government institutions have become increasingly aware of the commercial value of their research findings. These institutions are now more likely to enter into exclusive licensing agreements with commercial enterprises, including our competitors, to develop and market commercial products.

Our competitors may succeed in developing or licensing technologies and drugs that are more effective or less costly than the potential products we are developing. Our competitors may succeed in obtaining FDA or other regulatory approvals for drug candidates before we do. If competing drug candidates prove to be more effective or less costly than our drug candidates, our drug candidates, even if approved for sale, may not be able to compete successfully with our competitors' existing products or new products under development. If we are unable to compete successfully, we may never be able to sell enough of our potential products at a price sufficient to permit us to generate profits.

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We believe that due to the global political environment that time to market is critical in the discovery of an effective countermeasure to radiation exposure and other biological and chemical threats. New developments in areas in which we are conducting our research and development are expected to continue at a rapid pace in both industry and academia. It is due to these reasons that we believe that competition will be driven by time to market.

If our proposed product candidates are successfully developed and approved, we will face competition based on the safety and effectiveness of our proposed products, the timing and scope of regulatory approvals, availability of manufacturing, sales, marketing and distribution capabilities, reimbursement coverage, price and patent position. There can be no assurance that our competitors will not develop more effective or more affordable technology or products, or achieve earlier patent protection, product development or product commercialization than us. Accordingly, our competitors may succeed in commercializing products more rapidly or effectively than us, which could have a material adverse effect on our business, financial condition and results of operations.

GOVERNMENTAL REGULATION

Our research and development activities and the manufacturing and marketing of our applications are subject to the laws and regulations of governmental authorities in the U.S. and other countries in which our applications may be potentially marketed. Specifically, in the U.S., the FDA, among other activities, regulates new product approvals to establish safety and efficacy of these applications. Governmental authorities in the United States extensively regulate the pre-clinical and clinical testing, safety, efficacy, research, development, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution, among other things, of pharmaceutical products. Governments in other countries have similar requirements for testing and marketing. In the U.S., in addition to meeting FDA regulations, we are also subject to other federal laws as well as certain state laws.

REGULATORY PROCESS IN THE UNITED STATES

In the United States, the FDA, under the Federal Food, Drug, and Cosmetic Act (FFDCA), the Public Health Service Act and other federal statutes and regulations, subject pharmaceutical and biologic products to rigorous review. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our products or product candidates, and we may be criminally prosecuted. The FDA also has the authority to discontinue or suspend manufacture or distribution, require a product withdrawal or recall or revoke previously granted marketing authorizations, if we fail to comply with regulatory standards or if we encounter problems following initial marketing.

Approval of new pharmaceutical (and biological) products is a lengthy procedure leading from development of a new product through pre-clinical and clinical testing. This process takes a number of years and the expenditure of significant resources. There can be no assurance that our product candidates will ultimately receive regulatory approval.

Regardless of how our product candidates are regulated, the FFDCA and other Federal statutes and regulations govern or influence the research, testing, manufacture, safety, labeling, storage, record-keeping, approval, distribution, use, product reporting, advertising and promotion of such products. Noncompliance with applicable requirements can result in civil penalties, recall, injunction or seizure of products, refusal of the government to approve or clear product approval applications or to allow us to enter into government supply contracts, withdrawal of previously approved applications and criminal prosecution.

PRODUCT APPROVAL IN THE UNITED STATES

To obtain approval of a new product from the FDA, we must, among other requirements, submit data demonstrating the product's safety and efficacy, as well as, detailed information and reports on the manufacture and composition of the product candidate. In most cases, this entails extensive laboratory tests, pre-clinical and clinical trials. This testing and the preparation of necessary applications and processing of those applications by the FDA are expensive and typically take many years to complete. The FDA may deny our applications or may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing any products we may develop. The FDA also may require post-marketing testing and surveillance to monitor the effects of approved products or place conditions on any approvals that could restrict the commercial applications of these products. Regulatory authorities may withdraw product approvals if we fail to comply with regulatory standards or if we encounter problems following initial marketing. With respect to patented products or technologies, delays imposed by the governmental approval process may materially reduce the period during which we will have the exclusive right to exploit the products or technologies.

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The process required by the FDA before a new drug or biologic may be marketed in the United States generally involves the following:

completion of pre-clinical laboratory tests or trials and formulation studies;

submission to the FDA of an IND for a new drug or biologic, which must become effective before human clinical trials may begin;

performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug or biologic for its intended use; and,

submission and approval of a New Drug Application, or NDA, for a drug, or a Biologics License Application, or BLA, for a biologic.

Pre-clinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity. The results of pre-clinical testing, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application. The FDA requires a 30-day waiting period after the filing of each IND application before clinical trials may begin, in order to ensure that human research subjects will not be exposed to unreasonable health risks. At any time during this 30-day period or at any time thereafter, the FDA may halt proposed or ongoing clinical trials, or may authorize trials only on specified terms. The IND application process may become extremely costly and substantially delay development of our products. Moreover, positive results of pre-clinical tests will not necessarily indicate positive results in clinical trials.

The sponsor typically conducts human clinical trials in three sequential phases, which may overlap. These phases generally include the following:

Phase I: The product is usually first introduced into healthy humans or, on occasion, into patients, and is tested for safety, dosage tolerance, absorption, distribution, excretion and metabolism.

Phase II: The product is introduced into a limited patient population to:

assess its efficacy in specific, targeted indications;

assess dosage tolerance and optimal dosage; and

identify possible adverse effects and safety risks.

Phase III: These are commonly referred to as pivotal studies. If a product is found to have an acceptable safety profile and to be potentially effective in Phase II clinical trials, new clinical trials will be initiated to further demonstrate statistically significant clinical efficacy, optimal dosage and safety within an expanded and diverse patient population at geographically-dispersed clinical study sites.

If the FDA does ultimately approve the product, it may require post-marketing testing, including potentially expensive Phase IV studies, to monitor its safety and effectiveness.

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Clinical trials must meet requirements for Institutional Review Board, or IRB, oversight, informed consent and the FDA's Good Clinical Practices. Prior to commencement of each clinical trial, the sponsor must submit to the FDA a clinical plan, or protocol, accompanied by the approval of the committee responsible for overseeing clinical trials at one of the clinical trial sites. The FDA and the IRB at each institution at which a clinical trial is being performed may order the temporary or permanent discontinuation of a clinical trial at any time if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients.

The sponsor must submit to the FDA the results of the pre-clinical and clinical trials, together with, among other things, detailed information on the manufacturing and composition of the product, in the form of an NDA, or, in the case of a biologic, a BLA. Once the submission has been accepted for filing, the FDA has 180 days to review the application and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, but the FDA is not bound by the recommendation of an advisory committee.

It is possible that our product candidates will not successfully proceed through this approval process or that the FDA will not approve them in any specific period of time, or at all. The FDA may deny or delay approval of applications that do not meet applicable regulatory criteria, or if the FDA determines that the clinical data do not adequately establish the safety and efficacy of the product. Satisfaction of FDA pre-market approval requirements for a new biologic is a process that may take several years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. The FDA reviews these applications and, when and if it decides that adequate data are available to show that the product is both safe and effective and that other applicable requirements have been met, approves the drug or biologic for marketing. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon our activities. Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Upon approval, a product candidate may be marketed only for those indications approved in the BLA or NDA and may be subject to labeling and promotional requirements or limitations, including warnings, precautions, contraindications and use limitations, which could materially impact profitability. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-market regulatory standards is not maintained or if safety, efficacy or other problems occur after the product reaches the marketplace.

The FDA may, during its review of an NDA or BLA, ask for additional test data. If the FDA does ultimately approve the product, it may require post-marketing testing, including potentially expensive Phase IV studies, to monitor the safety and effectiveness of the product. In addition, the FDA may, in some circumstances, impose restrictions on the use of the product, which may be difficult and expensive to administer and may require prior approval of promotional materials.

Animal Efficacy Rule

Using traditional efficacy studies in the development of some of our potential applications would require healthy human volunteers to be exposed to lethal agents and pathogens. This cannot be done. Therefore, for several of the product opportunities we are pursuing, we may apply for approval based upon a rule adopted by the FDA in 2002, titled "Approval of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible" (Code of Federal Regulations, Title 21, Part 314, Subpart I), which is also referred to as the "animal efficacy rule." Pursuant to this rule, in situations where it would be unethical to conduct traditional Phase III efficacy studies in humans, as is the case with our applications relating to the treatment of maladies caused by exposure to high level gamma radiation and various chemical and biological agents, the FDA will review new drugs for approval on the basis of safety in humans and efficacy in relevant animal models. Under either the animal efficacy rule or traditional efficacy rules, we will not have

marketable applications unless and until our drug candidates complete all required safety studies and clinical trials and receive FDA approval in the United States or approval by regulatory agencies outside of the United States.

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ONGOING FDA REQUIREMENTS

Before approving an NDA or BLA, the FDA will inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facilities are in compliance with the FDA's current Good Manufacturing Practices, or cGMP, requirements which govern the manufacture, holding and distribution of a product. Manufacturers of biologics also must comply with the FDA's general biological product standards. Following approval, the FDA periodically inspects drug and biologic manufacturing facilities to ensure continued compliance with the cGMP requirements. Manufacturers must continue to expend time, money and effort in the areas of production, quality control, record keeping and reporting to ensure full compliance with those requirements. Failure to comply with these requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, voluntary recall of product, withdrawal of marketing approval or civil or criminal penalties. Adverse experiences with the product must be reported to the FDA and could result in the imposition of marketing restrictions through labeling changes or market removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

The labeling, advertising, promotion, marketing and distribution of a drug or biologic product also must be in compliance with FDA and FTC requirements which include, among others, standards and regulations for direct-to-consumer advertising, industry-sponsored scientific and educational activities, and promotional activities involving the internet. The FDA and FTC have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a Warning Letter directing the company to correct deviations from regulatory standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA and enforcement actions that can include seizures, injunctions and criminal prosecution.

Manufacturers are also subject to various state and Federal laws and regulations governing laboratory practices (specifically, the requirement for certain studies to comply with current Good Laboratory Practices), the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances in connection with their research. In each of the above areas, the FDA has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products and deny or withdraw approvals.

Some of our drug candidates may need to be administered using specialized drug delivery systems. We may rely on drug delivery systems that are already approved to deliver drugs like ours to similar physiological sites or, in some instances, we may need to modify the design or labeling of the legally available device for delivery of our product candidate. In such an event, the FDA may regulate the product as a combination product or require additional approvals or clearances for the modified device. Further, to the extent the delivery device is owned by another company, we would need that company's cooperation to implement the necessary changes to the device and to obtain any additional approvals or clearances. Obtaining such additional approvals or clearances, and cooperation of other companies, when necessary, could significantly delay, and increase the cost of obtaining, marketing approval, which could reduce the commercial viability of a drug candidate.

HIPAA REQUIREMENTS

Other federal legislation may affect our ability to obtain certain health information in conjunction with our research activities. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, mandates, among other things, the adoption of standards designed to safeguard the privacy and security of individually identifiable health information. In relevant part, the U.S. Department of Health and Human Services, or HHS, has released two rules to date mandating the use of new standards with respect to such health information. The first rule imposes new standards relating to the privacy of individually identifiable health information. These standards restrict the manner and

circumstances under which covered entities may use and disclose protected health information so as to protect the privacy of that information. The second rule released by HHS establishes minimum standards for the security of electronic health information. While we do not believe we are directly regulated as a covered entity under HIPAA, the HIPAA standards impose requirements on covered entities conducting research activities regarding the use and disclosure of individually identifiable health information collected in the course of conducting the research. As a result, unless they meet these HIPAA requirements, covered entities conducting clinical trials for us may not be able to share with us any results from clinical trials that include such health information.

In addition to the statutes and regulations described above, we are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state and local regulations.

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DISTRIBUTION

If Homspera, Radilex or Viprovex receives approval from the FDA, we will attempt to use our best efforts to commercialize these applications.

EMPLOYEES

Number of Employees

We currently have four employees: Michael K. Wilhelm, our Chief Executive Officer; John N. Fermanis, our Chief Financial Officer; and Hal N. Siegel, Ph.D., Vice-President and Chief Scientific Officer and a Scientific Development Manager. Due to our lack of working capital, all salaries are being accrued. From our inception through the period ended December 31, 2010, we have relied on the services of outside consultants in business and research development.

ITEM 1A. RISK FACTORS

You should carefully consider the risks described below together with all of the other information included in this report before making an investment decision. The risks described below are the material risks that we are currently aware of that are facing our company. In addition, other sections of this report may include additional factors that could adversely impact our business and operating results. If any of the following risks actually occurs, our business, financial condition or results of operations could be materially adversely affected. In that case, the trading price of our common stock would decline and you may lose all or part of your investment.

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Risks Related To Our Financial Results and Need for Additional Financing

We are in default on our senior secured debt obligations due to non-payment and have been notified of intent to sell collateral in public auction.

We have received Notification of Disposition of Collateral stating that due to continuing Events of Default, from YA Global Investments, L.P., a holder of senior secured debentures, intends to sell the collateral in public auction on June 7, 2011.

Previously, we had received a Guarantor Demand Letter and a Reservation of Rights Letter from YA Global Investments, L.P. after failure to, among other things, satisfy installment payments pursuant to terms of the agreement with to YA Global.

The Guarantor Demand Letter states YA Global has elected to accelerate the full unpaid Principal amount of the Debentures, together with accrued and unpaid interest and all other amounts owing and accordingly, demands us to immediately pay in full in cash all amounts due under the financing agreements with the Secured Debenture Holder. As of December 31, 2010, the aggregate liability due to was approximately $3.7 million.

In addition to restating these demands and rights, the Reservation of Rights Letter advises that so long as Events of Default are continuing, the interest rate set forth in the July 2010 Debenture shall be (24%) per annum and YA Global demands payment of all amounts due under the Debentures and other Financing Documents, including the entire Principal amount, all accrued and unpaid interest, and all fees, costs and costs of collection, including, attorney's fees and expenses. Further, the Reservation of Rights Letter advises that a Triggering Event has occurred and the Company failed to achieve one or more of the Triggering Milestones as defined in the agreements. As a consequence, the Conversion Price for the Debentures will become (80%) of the lowest daily Volume Weighted Average Price for the (30) Trading Days immediately prior to the applicable Conversion Date.

We have incurred losses since inception, have limited cash resources and anticipate that we will continue to incur substantial losses for the foreseeable future.

In the absence of significant revenue and profits, and since we do not expect to generate significant revenues in the foreseeable future, we, in order to fund the immediate future operations, will be completely dependent on additional debt and equity financing arrangements. In anticipation of the need to raise additional financing in the immediate future, we have commenced, and will continue to pursue, efforts to raise additional financing from a variety of sources and means. No assurance can be given that any such additional funding will be available or that, if available, can be obtained on terms favorable to us. If we are unable to raise needed funds on acceptable terms, we will not be able to develop or enhance our products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, we will not be able to continue operations

We expect losses to increase during the coming twelve months. We also do not expect to begin to generate significant revenue in the coming twelve months, and our costs are likely to increase as we continue our research and development efforts on our early, pre-clinical stage products and build out our corporate infrastructure.

We have a limited operating history and have not yet commercialized any products or generated any product revenues. We have always experienced negative cash flow and expect to continue to incur significant and increasing negative cash flow and operating losses.

We expect to continue to incur significant and increasing negative cash flow and operating losses as we continue our research activities, conduct development of, and seek regulatory approvals for our potential drug candidates. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, total assets and working capital.

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We have financed our operations and internal growth principally through the issuance of equity securities and convertible debt instruments. We have devoted substantially all of our efforts to research and development and we have not completed development of any drugs. Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the extent of any future losses, whether or when any of our product candidates will become commercially available, or when we will become profitable, if at all. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

We are continuing to seek alternative funding to satisfy the Secured Debenture Holder's rights. However, there can be no assurance that an additional source of funding will materialize. If we do not raise additional capital in the immediate future, the Company will have to cease our operations. This among other factors may indicate that the Company will be unable to continue as a going concern for a reasonable period of time.

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs and if we cannot raise needed additional capital in the future, we will be required to cease operations.

Until such time, if at all, as we receive adequate funding, we intend to continue to defer payment of all of our obligations which are capable of being deferred, which actions have resulted in some vendors demanding cash payment for their goods and services in advance, and other vendors refusing to continue to do business with us. We do not expect to generate a positive cash flow from our operations for at least several years, if at all, due to anticipated expenditures for research and development activities, administrative and marketing activities, and working capital requirements and expect to continue to attempt to raise further capital through one or more further private placements. In the absence of significant revenue and profits, and since we do not expect to generate significant revenues in the foreseeable future, we, in order to fund the immediate future operations, will be completely dependent on additional debt and equity financing arrangements. In anticipation of the need to raise additional financing in the immediate future, we have commenced, and will continue to pursue, efforts to raise additional financing from a variety of sources and means. No assurance can be given that any such additional funding will be available or that, if available, can be obtained on terms favorable to us. If we are unable to raise needed funds on acceptable terms, we will not be able to develop or enhance our products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, we will not be able to continue operations. Based on our operating expenses and anticipated research and development activities we believe that we will require an additional $3,500,000 to meet our expenses over the next 12 months.

We expect to incur significant expenses for our research and development programs and our general and administrative expenses. We will need substantial additional funding and may be unable to raise capital when needed or on attractive terms, particularly in the current economic environment. An inability to raise necessary funds would force us to delay, reduce or eliminate our research and development programs and if we cannot raise needed additional capital in the future, we will be required to cease operations.

We currently need additional financing to fund our immediate operating expenses. We are deferring almost all current payments until new funding, if any, is received. Our future capital requirements will depend on many factors, including:

- the scope and results of our research and development efforts and our preclinical development activities;

- the timing of, and the costs involved in, preparing regulatory submissions;

- the costs involved in preparing, filing, maintaining our patents, as well as, other patent-related costs,

- the extent to which we acquire or invest in businesses, products and technologies; and,

- our ability to establish collaborations and partnerships.

Until such time, if ever, as we can generate revenues, we expect to finance our cash needs through public or private equity offerings, debt financings and corporate collaboration and licensing arrangements. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, research programs or product candidates or grant licenses on terms that may not be favorable to us.

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If we cannot raise additional funds when needed, or on acceptable terms, we will not be able to continue to develop our drug candidates. We require substantial working capital to fund our operations. Since we do not expect to generate any revenues in the foreseeable future, in order to fund operations, we will be completely dependent on additional debt and equity financing arrangements. There is no assurance that any financing will be sufficient to fund our capital expenditures, working capital and other cash requirements beyond May 2011. No assurance can be given that any such additional funding will be available or that, if available, can be obtained on terms favorable to us. If we are unable to raise needed funds on acceptable terms, we will not be able to develop or enhance our products, take advantage of any future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, we will not be able to continue operations.

Our business and results of operations may be negatively impacted by general economic and financial market conditions and such conditions may exacerbate the other risks that affect our business.

The world's financial markets are currently experiencing significant turmoil, resulting in reductions in available credit, constraints in access to capital, extreme volatility in security prices, rating downgrades of investments and reduced valuations of securities generally. These economic conditions have had, and we expect will continue to have, an adverse impact on the pharmaceutical and biotechnology industries. Our business depends on our ability to raise substantial additional capital and to maintain and enter into new collaborative research, development and commercialization agreements with leading pharmaceutical and biotechnology companies. Current market conditions could impair our ability to raise additional capital when needed for our research and development programs, or on attractive terms. Recent economic conditions may result in prospective collaborators electing to defer entering into collaborative agreements with us or reduce the amount of discretionary investment that prospective collaborators may have available to invest in our business.

We are unable to predict the likely duration and severity of the current disruption in financial markets and adverse economic conditions in the U.S. and abroad, but the longer the duration the greater risks we face in operating our business. There can be no assurance, therefore, that current economic conditions or worsening economic conditions or a prolonged or recurring recession will not have a significant adverse impact on our operating results.

We have deferred, and may continue to defer, payment of some of our obligations, which may adversely affect our ability to obtain goods and services in the future.

We estimate that we will require approximately $6.0 million to meet our expenses for the next 24 months. Until such time, if at all, as we receive adequate funding, we intend to defer payment of all of our obligations that are capable of being deferred. Such deferment has resulted in the past, and may result in the future, in some vendors demanding cash payment for their goods and services in advance, and other vendors refusing to continue to do business with us and/or begin legal action to collect debts, which may adversely affect our ability to obtain goods and services in the future, or to do so on favorable terms. There is no guarantee that we will be able to defer payment of any of our obligations, at which point we will be forced to find immediate funding to settle such obligations. If we do not find such funding, we may not be able obtain the services and goods needed to continue our operations.

Our operating expenses are unpredictable, which may adversely affect our business, operations and financial condition.

As a result of our limited operating history and because of the emerging nature of the markets in which we will compete, our financial data is of limited value in planning future operating expenses. To the extent our operating expenses precede or are not rapidly followed by increased revenue, our business, results of operations and financial condition may be materially adversely affected. Our expense levels will be based in part on our expectations

concerning future revenues. We currently anticipate that a significant portion of any revenue would be derived from Homspera, Radilex and Viprovex; however, the size and extent of such revenues, if any, are wholly dependent upon the choices and demand of individuals, which are difficult to forecast accurately. We may be unable to adjust our operations in a timely manner to compensate for any unexpected shortfall in revenues. Further, business development and marketing expenses may increase significantly as we further our product development.

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If our stock price is volatile, purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies, particularly in recent months due to the turmoil in world financial markets. As a result of this volatility, investors may not be able to sell their common stock at or above the price at which they purchase it. The market price for our common stock may be influenced by many factors, including:

- results from pre-clinical studies of our potential product candidates or those of our competitors;
- regulatory developments in the United States and foreign countries;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

Risks Related to Development of Product Candidates

If we do not successfully develop, acquire or license new drugs our business may not grow.

We must invest substantial time, resources and capital in identifying and developing new drugs, dosage and delivery systems, either on our own or by acquiring and licensing such products from third parties. Our growth depends, in part, on our success in such process. If we are unable to either develop new products on our own or acquire licenses for new products from third parties, our ability to grow revenues and market share may be adversely affected. In addition, we may not be able to recover our investment in the development of new drugs, given that projects may be interrupted, unsuccessful, not as profitable as initially contemplated or we may not be able to obtain necessary financing for such development if we are unable to fund such development from our future revenues. Similarly, there is no assurance that we can successfully secure such rights from third parties on an economically feasible basis.

All our potential applications are derived from the use of Homspera. If Homspera is found to be unsafe or ineffective, our business would be materially harmed.

All of our current potential drug candidates are derived from Homspera. In addition, we plan to utilize Homspera in the development of any future products we market. If these current or future product candidates are found to be unsafe or ineffective due to the use of Homspera, we may have to modify or cease production of the products. As all of our applications utilize or will utilize Homspera, any findings that Homspera is unsafe or ineffective would severely harm our business operations, since all of our primary revenue sources would be negatively affected by such findings.

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We will need to conduct significant additional research, preclinical testing and clinical testing and expect to incur losses as we research, develop and seek regulatory approvals for our potential products.

All of our research and development efforts are early, pre-clinical stage and Homspera has only undergone exploratory studies to evaluate its biological activity in small animals. We will need to conduct significant additional research, pre-clinical testing and clinical testing before we can file applications with the FDA for approval of our product candidates. To date we have not yet made applications with the FDA or any other governmental regulatory agency for approval for our drug candidates, nor have we been in a position to seek such approval. Until such time as we are able to file a New Drug Application (NDA), and it is subsequently approved, we will not be able to market or manufacture any products.

If our potential products fail in clinical trials or do not gain regulatory approval, or if our products do not achieve market acceptance, we will not be profitable. If we fail to become and remain profitable, or if we are unable to fund our continuing losses, our business may fail. In addition, to compete effectively, any future products must be easy to use, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives.

If we do not obtain government regulatory approval for our products, we cannot commercialize our products, we will not generate revenues and our business would be materially harmed.

Our principal development efforts are currently centered on Homspera, and derivatives thereof, Radilex and Viprovex. All drug candidates require FDA and/or foreign government approvals before they can be commercialized. These regulations change from time to time and new regulations may be adopted. Our research and development efforts for our drug candidates are at a very early stage; they have not been, and may not be, approved for commercial sale by the FDA or any other governmental regulatory agency. We may incur significant additional operating losses over the next several years as we fund development, clinical testing and other expenses while seeking regulatory approval. To date we have conducted limited pre-clinical studies of our potential drug candidates using various small animal models; significant additional trials are required, and we may not be able to demonstrate that these drug candidates are safe or effective. If we are unable to demonstrate the safety and effectiveness of a particular drug candidate to the satisfaction of regulatory authorities, the drug candidate will not obtain required government approval. If we do not receive FDA or foreign approvals for our products, we will not be able to sell our potential products and will not generate revenues. Even if we receive regulatory approval of a potential product, such approval may impose limitations on the indicated uses for which we may market the product, which may limit our ability to generate significant revenues.

We depend on the success of our potential drug product candidate, Homspera, and its derivates Radilex and Viprovex, which are still under development. If we are unable to commercialize any of these product candidates, or experience significant delays in doing so, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the development of Homspera, and its derivates Radilex and Viprovex, for human stem cell stimulation, immune system stimulation and anti-infective activity, vaccine adjuvancy, and wound healing. Our ability to generate product revenues, which we do not expect in any case will occur for at least the next several years, will depend heavily on the successful development and commercialization of these product candidates. The commercial success of these product candidates will depend on several factors, including the following:

- successful completion of pre-clinical and clinical trials;
- receipt of marketing approvals from the FDA and similar foreign regulatory authorities;

establishing commercial manufacturing arrangements with third-party manufacturers;

launching commercial sales of the product, whether alone or in collaboration with others; and

acceptance of the product in the medical community and with third-party payors.

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If we are not successful in commercializing Homspera, Radilex or Viprovex, our business will be materially harmed. Our efforts to commercialize Homspera, and its derivates Radilex and Viprovex, are at an early stage. To date we have conducted limited pre-clinical studies of our potential drug candidates using various small animal models. Our current potential drug candidates will require significant additional research and development efforts and regulatory approvals prior to potential commercialization in the future. We cannot guarantee that we will ever obtain any regulatory approvals of Homspera, Radilex or Viprovex. We currently are focusing our core competencies on the development of Homspera, Radilex and Viprovex although there may be no assurance that we will be successful in so doing.

Our current potential drug candidates, Radilex, Viprovex and our technologies utilizing Homspera are at early stages of development and may not be shown to be safe or effective and may never receive regulatory approval. Neither Radilex nor Viprovex nor our technologies utilizing Homspera have yet been tested in large animals or humans. Regulatory authorities may not permit large animal or human testing of Radilex, Viprovex or any other potential products derived from Homspera. Even if large animal or human testing is permitted, none of Radilex, Viprovex or any other potential drug candidate, if any, derived from Homspera may be successfully developed or shown to be safe or effective.

The results of our pre-clinical studies may not be indicative of future pre-clinical or clinical trial results. A commitment of substantial resources to conduct time-consuming research, pre-clinical studies and clinical trials will be required if we are to develop any products. Delays in planned patient enrollment in our clinical trials may result in increased costs, program delays or both. None of our potential products or technologies may prove to be safe or effective in clinical trials. Approval of the FDA, or other regulatory approvals, including export license permissions, may not be obtained and even if successfully developed and approved, our potential products may not achieve market acceptance. Any potential products resulting from our programs may not be successfully developed or commercially available for a number of years, if at all.

Moreover, unacceptable toxicity or side effects could occur at any time in the course of human clinical trials or, if any products are successfully developed and approved for marketing, during commercial use of any of our proposed products. The appearance of any unacceptable toxicity or side effects could interrupt, limit, delay or abort the development of any of our proposed products or, if previously approved, necessitate their withdrawal from the market.

We will not be able to commercialize our product candidates if our preclinical studies do not produce successful results or our clinical trials do not demonstrate safety and efficacy in humans.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct, at our own expense, extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our product candidates. Preclinical and clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials or we may abandon projects that we expect to

be promising;

enrollment in our clinical trials, if any, may be slower than we currently anticipate, resulting in significant delays;

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- we might have to suspend or terminate our clinical trials, if any, if the participating patients are being exposed to unacceptable health risks;

- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;

- the cost of our clinical trials, if any, may be greater than we currently anticipate;

- any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the product not commercially viable; and

- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete our clinical trials or other testing or if the results of these trials or tests are not positive or are only modestly positive, we may:

- be delayed in obtaining marketing approval for our product candidates;

- not be able to obtain marketing approval; or

- obtain approval for indications that are not as broad as intended.

Our product development costs will also increase if we experience delays in testing or approvals. Significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or product candidates.

The lengthy product approval process and uncertainty of government regulatory requirements may delay or prevent us from commercializing proposed products, and therefore adversely affect the timing and level of future revenues, if any.

The process of obtaining FDA and other regulatory approvals is time consuming, expensive and difficult to design and implement. Our current drug candidates, Homspera, Radilex and Viprovex, will have to undergo clinical trials and the marketing and manufacturing of these drug candidates, if any, will be subject to rigorous testing procedures. Our research and development efforts are at a very early stage and Homspera, Radilex and Viprovex have only undergone pre-clinical testing in small animals. We may not be able to obtain the necessary approvals for clinical trials, manufacturing or marketing of Homspera, Radilex and Viprovex or any other potential products, if any, derived from Homspera. Moreover, any significant delays in clinical trials will impede our ability to commercialize our applications and generate revenue and could significantly increase our development costs. The commencement and completion of clinical trials for Homspera, Radilex, Viprovex or any other potential products, if any, derived from Homspera, could be delayed or prevented by a variety of factors, including:

- delays in obtaining regulatory approvals to commence a study;

delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;

delays in the enrollment of patients;

lack of efficacy during clinical trials; or,

unforeseen safety issues.

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Even if marketing approval from the FDA is received, the FDA may impose post-marketing requirements, such as:

- labeling and advertising requirements, restrictions or limitations, including the inclusion of warnings, precautions, contra-indications or use limitations that could have a material impact on the future profitability of our applications;
- testing and surveillance to monitor our future products and their continued compliance with regulatory requirements;
- submitting products for inspection and, if any inspection reveals that the product is not in compliance, prohibiting the sale of all products;
- suspending manufacturing; or
- withdrawing marketing clearance.

Additionally, the FDA's policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our applications. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market our potential future products and our business could suffer.

Even if human clinical trials of Radilex, Viprovex or any other potential products, if any, derived from Homspera are initiated and successfully completed, the FDA may not approve any of them for commercial sale. We may encounter significant delays or excessive costs in our efforts to secure necessary approvals. Regulatory requirements are evolving and uncertain. Future United States or foreign legislative or administrative acts could also prevent or delay regulatory approval of our products. We may not be able to obtain the necessary approvals for clinical trials, manufacturing or marketing of any of our potential products under development. Even if commercial regulatory approvals are obtained, they may include significant limitations on the indicated uses for which a product may be marketed.

The FDA has not designated expanded access protocols for Homspera, Radilex or Viprovex as "treatment" protocols. The FDA may not determine that Homspera, Radilex or Viprovex meet all of the FDA's criteria for use of an investigational drug for treatment use. Even if Homspera or Radilex or Viprovex are allowed for treatment use, third party payers may not provide reimbursement for the costs of treatment with any of them. The FDA also may not consider any of Homspera, Radilex or Viprovex to be an appropriate candidate for acceptance as Emergency Use Authorization for Promising Medical Countermeasures Under Development, accelerated approval, expedited review or fast track designation.

Risks Related to Our Dependence on Third Parties for Manufacturing, Research and Development and Marketing and Distribution Activities

If third parties do not manufacture our product candidates in sufficient quantities and at an acceptable cost, clinical development and commercialization of our product candidates could be delayed, prevented or impaired.

For the manufacture of Radilex, Viprovex and Homspera, we obtain synthetic peptides from third party manufacturers. If any of these proposed manufacturing operations prove inadequate, there may be no assurance that any other arrangements may be established on a timely basis or that we could establish other manufacturing capacity on a timely basis. Our dependence on such manufacturers may delay or impair our ability to generate revenues, or

adversely affect our profitability.

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We do not currently have manufacturing facilities or personnel to independently manufacture our peptides. We rely and expect to continue to rely on third parties for the production of clinical and commercial quantities of our product candidates. There are a limited number of manufacturers that operate under the FDA's cGMP regulations and that are both capable of manufacturing for us and willing to do so. We do not have any long-term manufacturing agreements with third parties, and manufacturers under our short-term supply agreements are not obligated to accept any purchase orders we may submit. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop product candidates and commercialize any products that receive regulatory approval on a timely and competitive basis. In particular, if the third parties that are currently manufacturing Homspera for our preclinical studies should cease to continue to do so for any reason, we expect that we would experience delays in advancing these studies while we identify and qualify replacement suppliers.

Use of third-party manufacturers may increase the risk that we will not have adequate supplies of our product candidates.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party; and
- the possible termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us.

If we are not able to obtain adequate supplies of our product candidates and any approved products, it will be more difficult for us to develop our product candidates and compete effectively. Our product candidates and any products that we successfully develop may compete with product candidates and products of third parties for access to manufacturing facilities.

Our contract manufacturers are subject to ongoing, periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with cGMP regulations and other governmental regulations and corresponding foreign standards. We cannot be certain that our present or future manufacturers will be able to comply with cGMP regulations and other FDA regulatory requirements or similar regulatory requirements outside the United States. We do not control compliance by our contract manufacturers with these regulations and standards. Failure of our third-party manufacturers or us to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and products.

If third parties on whom we rely on for our research and development activities and pre-clinical studies do not perform as contractually required or as we expect or fail to comply with all applicable regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates, and our business may suffer.

We do not have the ability to independently conduct the research and development activities and pre-clinical studies required for regulatory submissions and eventual regulatory approval for our products. We depend on independent clinical investigators, contract research organizations and other third-party service providers to conduct the clinical trials of our product candidates and expect to continue to do so for at least the next several years.

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We rely heavily on independent clinical investigators, contract research organizations and other third-party service providers for successful execution of our pre-clinical studies, but do not control many aspects of their activities. We are responsible for ensuring that each of our studies, and clinical trials, if any, is conducted in accordance with the general investigational plan and protocols for the study. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, for conducting and recording and reporting the results of clinical trials, if any, to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA closely monitors the progress of clinical trials that are conducted in the U.S., and the FDA significantly expands the federal government's clinical trial registry to cover more trials and more information, including information on the results of completed trials. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain protection for the intellectual property relating to our technology and products, the value of our technology and products will be adversely affected.

Our success will depend in large part on our ability to obtain and maintain protection in the United States and other countries for the intellectual property covering or incorporated into our technology and products. The patent situation in the field of biotechnology and pharmaceuticals generally is highly uncertain and involves complex legal and scientific questions. We may not be able to obtain additional issued patents relating to our technology or products. Even if issued, patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection we may have for our products. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

Our patents also may not afford us protection against competitors with similar technology. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications.

We have filed patent applications directed to various methods of using and compositions comprising Substance P analogues. As of December 31, 2010 we owned approximately fourteen issued patents, including three issued U.S. patents and eleven issued foreign patents. Also as of December 31, 2010 we had approximately twenty-three pending patent applications and twelve filed and waiting for review. All inventions embodied in these applications and issued patents have been assigned to the company by the inventors. In addition, we have entered into a license agreement with the University of Pittsburgh whereby we have licensed the University's ownership interest to a patent that was jointly filed with the University of Pittsburgh.

Our success will depend in part on our ability to obtain additional United States and foreign patent protection for our drug candidates and processes, preserve our trade secrets and operate without infringing the proprietary rights of third parties. We place considerable importance on obtaining patent protection for significant new technologies, products and processes.

If we fail to obtain or maintain these protections, we may not be able to prevent third parties from using our proprietary rights. Our currently pending or future patent applications may not result in issued patents. In the United States, patent applications are confidential until patent applications are published or the patent is issued, and because third parties may have filed patent applications for technology covered by our pending patent applications without us being aware of those applications, our patent applications may not have priority over any patent applications of others. In addition, our issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products or provide us with any competitive advantage. If a third party initiates litigation regarding our patents, and is successful, a court could revoke our patents or limit the scope of coverage for those patents.

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Legal standards relating to the validity of patents covering pharmaceutical and biotechnology inventions and the scope of claims made under such patents are still developing. In some of the countries in which we intend to market our products, pharmaceuticals are either not patentable or have only recently become patentable. Past enforcement of intellectual property rights in many of these countries has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries may be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions. The U.S. Patent and Trademark Office, commonly referred to as the USPTO, and the courts have not consistently treated the breadth of claims allowed in biotechnology patents. If the USPTO or the courts begin to allow broader claims, the incidence and cost of patent interference proceedings and the risk of infringement litigation will likely increase. On the other hand, if the USPTO or the courts begin to allow narrower claims, the value of our proprietary rights may be limited. Any changes in or unexpected interpretations of the patent laws may adversely affect our ability to enforce our patent position.

We also rely upon trade secrets, proprietary know-how and continuing technological innovation to remain competitive. We protect this information with reasonable security measures, including the use of confidentiality agreements with our employees, consultants and corporate collaborators. It is possible that these individuals will breach these agreements and that any remedies for a breach will be insufficient to allow us to recover our costs. Furthermore, our trade secrets, know-how and other technology may otherwise become known or be independently discovered by our competitors.

Our rights to the US Patent Nos. 5,945,508 and 5,998,376, Substance P Treatment for Immunostimulation, are limited by the rights of the University of Arizona and the United States Air Force and as a result, our ability to use the patent in our business is also limited. Due to these limitations, we may not be able to use the patent in the most profitable or efficient manner and, as a result, our results of operations may suffer. If patents are issued for any of our pending patent applications, the same limitations would most likely apply.

Our agreements with the University of Arizona outline very specific rights in regard to our sponsored-supported projects. In accordance with our sponsored-supported project agreements, the University of Arizona retains the right to use data developed during these projects for non-commercial purposes, including teaching, research and education.

Further, because our patents are based on research funded by the government, the U.S. Government has certain rights in any technology developed. These rights include a non-exclusive, paid-up, worldwide license under such inventions for any governmental purpose. In addition, under the federal Bayh Dole Act, a party which acquires an exclusive license for an invention that was partially funded by a federal research grant is subject to the following government rights: (i) products using the invention which are sold in the U.S. are to be manufactured substantially in the U.S. unless a waiver is obtained; (ii) the government may force the granting of a license to a third party who will make and sell the needed product if the licensee does not pursue reasonable commercialization of a needed product using the invention; and (iii) the U.S. Government may use the invention for its own needs.

As a result, our potential future revenues, if any, may be lessened. Additionally, our profit margins, if any, may be lessened as our cost of goods may increase if we are mandated to manufacture our products substantially in the United States. Additionally, the U.S. Government may elect to manufacture and use any products based on our technology without paying us any revenue.

Our patents and proprietary technology may not be enforceable and the patents and proprietary technology of others may prevent us from commercializing products, which would adversely affect our level of future revenues, if any.

Although we believe our proprietary technology to be protected and our patents on the use of Homspera and its derivates, Radilex and Viprovex are enforceable, the failure to obtain meaningful patent protection for our potential products and processes would greatly diminish the value of our potential products and processes.

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In addition, whether or not our applications are issued, or issued with limited coverage, others may receive patents that contain claims applicable to our potential products. Patents we are not aware of may adversely affect our ability to develop and commercialize any potential products.

The patent positions of biotechnology and pharmaceutical companies are often highly uncertain and involve complex legal and factual questions. Therefore, the breadth of claims allowed in biotechnology and pharmaceutical patents cannot be predicted. We also rely upon non-patented trade secrets and know how, and others may independently develop substantially equivalent trade secrets or know how. We also rely on protecting our proprietary technology in part through confidentiality agreements with our current and former corporate collaborators, employees, consultants and certain contractors. These agreements may be breached, and we may not have adequate remedies for any such breaches. Litigation may be necessary to defend against claims of infringement, to enforce our patents or to protect trade secrets. Litigation could result in substantial costs and diversion of management efforts regardless of the results of the litigation. An adverse result in litigation could subject us to significant liabilities to third parties, require disputed rights to be licensed or require us to cease using certain technologies.

Our potential products based on Homspera could infringe on the intellectual property rights of others, which may cause us to engage in costly litigation and, if not successful, could cause us to pay substantial damages and prohibit us from selling our products. Because patent applications in the United States are not publicly disclosed until the patent application is published or the patent is issued, applications may have been filed which relate to services similar to those offered by us. We may be subject to legal proceedings and claims from time to time in the ordinary course of our business, including claims of alleged infringement of the trademarks and other intellectual property rights of third parties.

If our potential products violate third-party proprietary rights, we cannot assure you that we would be able to arrange licensing agreements or other satisfactory resolutions on commercially reasonable terms, if at all. Any claims made against us relating to the infringement of third-party proprietary rights could result in the expenditure of significant financial and managerial resources and injunctions preventing us from providing services. Such claims could severely harm our financial condition and ability to compete.

In addition, if another party claims the same subject matter or subject matter overlapping with the subject matter that we have claimed in a United States patent application or patent, we may decide or be required to participate in interference proceedings in the USPTO in order to determine the priority of invention. Loss of such an interference proceeding would deprive us of patent protection sought or previously obtained and could prevent us from commercializing our potential products. Participation in such proceedings could result in substantial costs, whether or not the eventual outcome is favorable. These additional costs could adversely affect our financial results.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely upon unpatented proprietary technology, processes and know-how. We seek to protect this information in part by confidentiality agreements with our employees, consultants and third parties. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors. If we are unable to protect the confidentiality of our proprietary information and know-how, competitors may be able to use this information to develop products that compete with our products, which could adversely impact our business.

If we infringe or are alleged to infringe intellectual property rights of third parties, it will adversely affect our business.

Our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, may infringe or be claimed to infringe upon patents or patent applications under which we do not hold licenses or other rights. Third parties may own or control these patents and patent applications in the United States and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

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As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose or be required to seek a license from the third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the United States Patent and Trademark Office and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and technology. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Risks Related to Regulatory Approval of Our Product Candidates

If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. We have not received regulatory approval to market any of our product candidates in any jurisdiction. We have only limited experience in filing and prosecuting the applications necessary to gain regulatory approvals and expect to rely on third-party contract research organizations to assist us in this process. Securing FDA approval requires, among other things, the submission of extensive preclinical and clinical data, information about product manufacturing processes and supporting information to the FDA for each therapeutic indication and inspection of facilities to establish the product candidate’s safety and efficacy. Our future products may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may delay or prevent regulatory approval of an application. The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing or negative, inconsistent or inconclusive results obtained from preclinical or clinical trials could delay, limit or prevent regulatory approval of a product candidate.

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Our products could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements, or if we experience unanticipated problems with our products, when and if any of them are approved.

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory bodies. These requirements include, among other things, submissions of safety and other post-marketing information and reports, registration requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in:

- restrictions on such products, manufacturers or manufacturing processes;
- warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- required labeling changes;
- required post-marketing studies or clinical trials;
- distribution and use restrictions;
- voluntary recall;
- fines;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of our products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

Failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our products abroad.

We intend to market our products, if approved, outside the United States. In order to market our products in the European Union and other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. With respect to some of our product candidates, our collaborator has, or we expect that a future collaborator will have, responsibility to obtain regulatory approvals outside the United

States, and we will depend on our collaborators to obtain these approvals. The approval procedure varies among countries and can involve additional testing and additional review periods. The time required to obtain approval may differ from and may be longer than that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval as well as additional risks. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. We and our collaborators may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

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Risks Related to Commercialization

The commercial success of any products that we may develop will depend upon the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community.

Any products that we bring to the market may not gain market acceptance by physicians, patients, healthcare payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate material product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of any side effects;
- the efficacy and potential advantages over alternative treatments;
- the ability to offer our product candidates for sale at competitive prices;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate product revenues.

We do not have a sales organization and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties. Currently, we plan to build a focused specialty sales and marketing infrastructure to market or copromote some of our product candidates if and when they are approved. There are risks involved with establishing our own sales and marketing capabilities, as well as in entering into arrangements with third parties to perform these services. For example, developing a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed as a result of FDA requirements or other reasons, we would incur related expenses too early relative to the product launch. This may be costly, and our investment would be lost if we cannot retain our sales and marketing personnel. In addition, marketing and promotion arrangements in the pharmaceutical industry are heavily regulated, and many marketing and promotional practices that are common in other industries are prohibited or restricted. These restrictions are often ambiguous and subject to conflicting interpretations, but carry severe administrative, civil, and criminal penalties for noncompliance. It may be costly to implement internal controls to facilitate compliance by our sales and marketing personnel.

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If we are unable to obtain adequate reimbursement from third-party payors for any products that we may develop or acceptable prices for those products, our revenues and prospects for profitability will suffer.

Most patients will rely on Medicare and Medicaid, private health insurers and other third-party payors to pay for their medical needs, including any drugs we or our collaborators may market. If third-party payors do not provide adequate coverage or reimbursement for any products that we may develop, our revenues and prospects for profitability will suffer.

Regulatory approval to market a drug product does not assure that the product will be eligible for coverage by third-party payors or, assuming it is covered, that it will receive a profitable price. The process for obtaining third-party coverage and payment is costly and time-consuming. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. Our products may not be considered medically necessary or cost- effective. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Coverage through the Medicare prescription drug benefit program may increase demand for our products, but participating suppliers are required to negotiate prices with drug procurement organizations on behalf of Medicare beneficiaries. These prices are likely to be lower than we might otherwise obtain. Future legislation might allow government agencies to negotiate prices directly with drug companies, which could lead to even lower prices. Drugs sold to state-operated Medicaid programs are subject to mandatory rebate agreements that require quarterly payments to states based on the drug's average manufacturer price and best price. Private, non-governmental third-party payors frequently base their coverage policies and the prices they are willing to pay on the policies and payment rates under the Medicare and Medicaid programs.

A primary trend in the United States healthcare industry is toward cost containment. Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved healthcare products. In particular, third-party payors may limit the indications for which they will reimburse patients who use any products that we may develop. Cost control initiatives could decrease the price we might establish for products that we may develop, which would result in lower product revenues to us.

U.S. drug prices may be further constrained by possible Congressional action regarding drug reimportation into the United States. Legislation proposed in past Congressional sessions would allow the reimportation of approved drugs originally manufactured in the United States back into the United States from other countries where the drugs are sold at a lower price. Some governmental authorities in the U.S. are pursuing lawsuits to obtain expanded reimportation authority. Such legislation, regulations, or judicial decisions could reduce the prices we receive for any products that we may develop, if approved, negatively affecting our revenues and prospects for profitability. Alternatively, in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of reimportation, which could also reduce the revenue we generate from our product sales. Even without legislation authorizing reimportation, patients have been purchasing prescription drugs from Canadian and other non-United States sources, which has reduced the price received by pharmaceutical companies for their products.

In addition, in some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization of our products.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of any products that we may develop.

We face an inherent business risk of exposure to product liability claims in the event that the use of our technologies or products is alleged to have resulted in adverse side effects. Side effects or marketing or manufacturing problems pertaining to any of our products could result in product liability claims or adverse publicity. These risks will exist for those products in clinical development and with respect to those products that receive regulatory approval for commercial sale. Even though we have not historically experienced any problems associated with claims by users of our products, we do currently maintain product liability insurance.

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If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We do not have product liability insurance. We intend to purchase insurance coverage to include clinical trials and the sale of commercial products if we obtain marketing approval for any products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost and we may not be able to obtain insurance coverage that will be adequate to satisfy any liability that may arise. An inability to obtain product liability insurance at acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of our products. A product liability claim could hurt our financial performance. Even if we avoid liability exposure, significant costs could be incurred that could hurt our financial performance.

We face substantial competition which may result in others discovering, developing or commercializing products before or more successfully than we do.

The pharmaceutical industry is highly competitive. We face competition with respect to our current product candidates and any products we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Our competitors may develop products that are more effective, safer, more convenient or less costly than any that we are developing. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours. We believe that our most significant competitors in the area of drugs that work by modulating the activity of ion channels are large pharmaceutical companies which have internal ion channel drug discovery groups as well as smaller more focused companies engaged in ion channel drug discovery.

There are approved products on the market for all of the diseases and indications for which we are developing products. In many cases, these products have well known brand names, are distributed by large pharmaceutical companies with substantial resources and have achieved widespread acceptance among physicians and patients. In addition, we are aware of product candidates of third parties that are in development, which, if approved, would compete against product candidates for which we receive marketing approval.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to or necessary for our programs or

advantageous to our business.

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Our business activities involve the use of hazardous materials, which require compliance with environmental and occupational safety laws regulating the use of such materials. If we violate these laws, we could be subject to significant fines, liabilities or other adverse consequences.

Our research and development processes involve the controlled storage, use and disposal of hazardous materials, biological hazardous materials and radioactive compounds. Accordingly, we are subject to federal, state and local laws governing the use, handling and disposal of these materials. Although we believe that our safety procedures for handling and disposing of these materials comply in all material respects with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In addition, our collaborators may not comply with these laws. In the event of an accident or failure to comply with environmental laws, we could be held liable for damages that result, and any such liability could exceed our assets and resources. Current or future environmental laws or regulations may have a material adverse effect on our operations, business and assets.

Risks Related to Employees and Growth

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop or commercialize our product candidates.

Our success depends on our continued ability to attract, retain and motivate highly qualified managerial and key scientific personnel. We consider retaining Mr. Michael K. Wilhelm, our president and chief executive officer, and Dr. Hal N. Siegel, our vice president and director of our science department, to be key to our efforts to develop and commercialize our product candidates. All of our employees are at-will employees and can terminate their employment at any time. We currently maintain a key-man insurance policy on Mr. Wilhelm and Dr. Siegel for $1,000,000 and $250,000 respectively, payable to the company, on their lives. While we have entered into employment agreements with Mr. Wilhelm and Dr. Siegel, the loss of any of their services would be detrimental to us and could have a material adverse effect on our business, financial condition and results of operations.

In addition, as our business plan is implemented, we will need to recruit and retain additional management and key employees in virtually all phases of our operations. We cannot assure that we will be able to successfully attract and retain key personnel.

Risks Relating to Our Private Placements

Mandatory redemption of our convertible debentures could have a material adverse effect on our liquidity and cash resources.

If we are required to redeem all or any portion of our outstanding convertible debentures, it may have a material adverse effect on our liquidity and cash resources, and may impair our ability to continue to operate. If we are required to repurchase all or a portion of the debentures and do not have sufficient cash to make the repurchase, we may be required to obtain third party financing to do so, and there can be no assurances that we will be able to secure financing in a timely manner and on favorable terms, which could have a material adverse effect on our financial performance, results of operations and stock price. Furthermore, additional equity financing may be dilutive to the holders of our common stock, and debt financing, if available, may involve restrictive covenants, and strategic relationships, if necessary to raise additional funds, may require that we relinquish valuable rights.

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We have pledged all of our assets, including our intellectual property, in our subsidiaries as security for our outstanding secured convertible debentures.

Obligations under our outstanding convertible debentures are guaranteed by our wholly-owned subsidiary, ImmuneRegen, and secured by all of ImmuneRegen's assets and property, including its patents. Upon the occurrence of certain events of default defined in the convertible debentures, including our failure to pay the holder any amount of principal, interest, or other amounts when due, the full principal amount of the convertible debentures, together with interest and other amounts due, become immediately due and payable. In addition, in the event we effect any "fundamental transaction" as defined in the convertible debentures, including a merger or consolidation or sale of more than 50% of our assets, the holder may require the redemption of all amounts owed, including principal, accrued and unpaid interest and any other charges. We cannot assure you that we will have sufficient financial resources, or will be able to arrange financing, to redeem or retire our convertible debentures upon maturity. Any failure to redeem or retire the debentures when required will result in an event of default, and in such event, we may lose all of our assets, be forced to restructure, file for bankruptcy or cease operations, any of which could cause to you to lose all or part of your investment.

Conversion of our outstanding convertible notes may adversely affect the market price of our common stock and your rights in us may be reduced.

In 2010 the Company and YA Global Investments, L.P. entered into an agreement to amend two secured convertible debentures held by YA Global dated January 3, 2008 and June 12, 2008 in the amount of $2,000,000 and $1,000,000, respectively. The debentures per the agreement are amended to: (i) extend the maturity dates to December 31, 2011; (ii) increase the annual interest rate from ten percent (10.0%) to thirteen percent (13.0%); (iii) eliminate the $1,500,000 optional redemption provision; (iv) reduce the conversion price of the debentures to a range between $0.13 and $0.45; and, (v) require the Company pay a monthly installment amount of $42,000 in cash, stock or a combination thereof to YA Global as a reduction of the outstanding debt obligation.

Per the agreement, the conversion price of the $2,000,000 note prior to the occurrence of any triggering event, will be $0.13 for the first $1,500,000 converted and $0.17 for the remaining $500,000 converted. The conversion price of the $1,000,000 note prior to the occurrence of any triggering event has been reduced to be $0.17 for the first $500,000 converted and $0.22 for the remaining $500,000 converted. For both notes, following the occurrence of any triggering event, the conversion price shall be eighty percent (80%) of the lowest daily volume weighted average price for the thirty (30) trading days immediately prior to the applicable conversion date.

With regard to the $42,000 monthly installment payment, the Company shall pay to the holder by converting the installment amount into shares of common stock of the Company at the lowest conversion price then available, provided that there is not an equity conditions failure and volume limitations, based on the prior 20 trading days, allow. Any amount in excess of the volume limitation must be paid in cash unless this restriction is waived for that period. The Company may, at its option following notice to the holder, redeem such installment amount in cash or by any combination of both. Further, so long as no event of default has occurred and is continuing and the Company has paid to the holder all prior installment amounts, the Holder agrees to not convert any portion of this debenture during the calendar month immediately following the applicable installment date.

Furthermore, on July 19, 2010 the Company and YA Global entered into an agreement to amend, restate and consolidate into one debenture all 0% interest convertible debentures previously issued quarterly to YA Global beginning September 30, 2008 through June 30, 2010. The total principal due under the secured convertible note is $593,888.84 with an annual interest rate of 13.0% and maturing on December 31, 2011. The conversion price of the note prior to the occurrence of any triggering event, will be $0.25 for the first $143,888.54 converted, $0.30 for the next $75,000.00 converted, $0.35 for the following $75,000.00 converted and $0.45 for the remaining $300,000.30

converted. Following the occurrence of any triggering event, the conversion price shall be eighty percent (80%) of the lowest daily volume weighted average price for the thirty (30) trading days immediately prior to the applicable conversion date.

There are restrictive covenants in our convertible debentures relating to our ability to incur future indebtedness.

Our outstanding convertible debentures issued in July 2010 to YA Global Advisors, LLC (the "YA Global Debentures") limit our and ImmuneRegen's ability to incur indebtedness, other than certain types of permitted indebtedness, without the approval and waiver of YA Global.. Additionally, the YA Debentures prohibit us and ImmuneRegen from entering into or creating any liens, other than certain permitted liens, on our and ImmuneRegen's assets or any income derived from such assets. Our principal source of liquidity has historically been the sale of equity securities and debt securities. The holders of the YA Global Debentures may not permit us to incur additional indebtedness to fund our operations, which could cause a material adverse effect on our business and results of operations.

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General Company Related Risks

Sales or issuances of additional equity securities may adversely affect the market price of our common stock and your rights in us may be reduced.

In 2010 the Company and YA Global Investments, L.P. entered into an agreement to amend two secured convertible debentures held by YA Global dated January 3, 2008 and June 12, 2008 in the amount of $2,000,000 and $1,000,000, respectively. The debentures per the agreement are amended to: (i) extend the maturity dates to December 31, 2011; (ii) increase the annual interest rate from ten percent (10.0%) to thirteen percent (13.0%); (iii) eliminate the $1,500,000 optional redemption provision; (iv) reduce the conversion price of the debentures to a range between $0.13 and $0.45; and, (v) require the Company pay a monthly installment amount of $42,000 in cash, stock or a combination thereof to YA Global as a reduction of the outstanding debt obligation.

Per the agreement, the conversion price of the $2,000,000 note prior to the occurrence of any triggering event, will be $0.13 for the first $1,500,000 converted and $0.17 for the remaining $500,000 converted. The conversion price of the $1,000,000 note prior to the occurrence of any triggering event has been reduced to be $0.17 for the first $500,000 converted and $0.22 for the remaining $500,000 converted. For both notes, following the occurrence of any triggering event, the conversion price shall be eighty percent (80%) of the lowest daily volume weighted average price for the thirty (30) trading days immediately prior to the applicable conversion date.

With regard to the $42,000 monthly installment payment, the Company shall pay to the holder by converting the installment amount into shares of common stock of the Company at the lowest conversion price then available, provided that there is not an equity conditions failure and volume limitations, based on the prior 20 trading days, allow. Any amount in excess of the volume limitation must be paid in cash unless this restriction is waived for that period. The Company may, at its option following notice to the holder, redeem such installment amount in cash or by any combination of both. Further, so long as no event of default has occurred and is continuing and the Company has paid to the holder all prior installment amounts, the Holder agrees to not convert any portion of this debenture during the calendar month immediately following the applicable installment date.

Furthermore, on July 19, 2010 the Company and YA Global entered into an agreement to amend, restate and consolidate into one debenture all 0% interest convertible debentures previously issued quarterly to YA Global beginning September 30, 2008 through June 30, 2010. The total principal due under the secured convertible note is $593,888.84 with an annual interest rate of 13.0% and maturing on December 31, 2011. The conversion price of the note prior to the occurrence of any triggering event, will be $0.25 for the first $143,888.54 converted, $0.30 for the next $75,000.00 converted, $0.35 for the following $75,000.00 converted and $0.45 for the remaining $300,000.30 converted. Following the occurrence of any triggering event, the conversion price shall be eighty percent (80%) of the lowest daily volume weighted average price for the thirty (30) trading days immediately prior to the applicable conversion date.

Additionally, some of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act (“Rule 144”), subject to certain limitations, which were eased significantly in February 2008. Although we are a former shell company and thus subject to heightened informational requirements under revised Rule 144, we satisfied the requirement of filing “Form 10” information, as specified in the Rule, over 12 months ago. As a result, in general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who has satisfied a one-year holding period may freely sell their shares of our common stock, while our current and recent affiliates may sell, within any three-month period, a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to

such sale. Any substantial sale of common stock pursuant to any resale prospectus or Rule 144 may have an adverse effect on the market price of our common stock by creating an excessive supply.

Our stockholders may experience substantial dilution and a reduction in the price that they are able to obtain upon sale of their shares. Also, any new equity securities issued, including any new series of preferred stock authorized by our Board of Directors, may have greater rights, preferences or privileges than our existing common stock. To the extent stock is issued or options and warrants are exercised, holders of our common stock will experience further dilution. In addition, as in the case of the warrants, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities and upon the exercise of options and warrants, security holders may experience additional dilution.

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A limited prior public market and trading market may cause volatility in the price of our common stock.

Our common stock is currently traded on a limited basis on the FINRA OTC Bulletin Board (the "OTCBB") under the symbol "IRBS". The OTCBB is an inter-dealer, Over-The-Counter market that provides significantly less liquidity than exchanges such as the NASDAQ Stock Market and the NYSE Amex. Therefore, prices for securities traded solely on the OTCBB may be difficult to obtain and holders of common stock may be unable to resell their securities at or near their original offering price or at any price.

The quotation of our common stock on the OTCBB does not assure that a meaningful, consistent and liquid trading market currently exists, and in recent years such market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is thus subject to this volatility.

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

Our common stock is considered to be a "penny stock" since it does not qualify for one of the exemptions from the definition of "penny stock" under Section 3a51-1 of the Securities Exchange Act for 1934 as amended (the "Exchange Act"). Our common stock is a "penny stock" because it meets one or more of the following conditions (i) the stock trades at a price less than $5.00 per share; (ii) it is NOT traded on a "recognized" national exchange; (iii) it is NOT quoted on the Nasdaq Stock Market, or even if so, has a price less than $5.00 per share; or (iv) is issued by a company that has been in business less than three years with net tangible assets less than $5 million.

The principal result or effect of being designated a "penny stock" is that securities broker-dealers participating in sales of our common stock will be subject to the "penny stock" regulations set forth in Rules 15-2 through 15g-9 promulgated under the Exchange Act. For example, Rule 15g-2 requires broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document at least two business days before effecting any transaction in a penny stock for the investor's account. Moreover, Rule 15g-9 requires broker-dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any penny stock to that investor. This procedure requires the broker-dealer to (i) obtain from the investor information concerning his or her financial situation, investment experience and investment objectives; (ii) reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has sufficient knowledge and experience as to be reasonably capable of evaluating the risks of penny stock transactions; (iii) provide the investor with a written statement setting forth the basis on which the broker-dealer made the determination in (ii) above; and (iv) receive a signed and dated copy of such statement from the investor, confirming that it accurately reflects the investor's financial situation, investment experience and investment objectives. Compliance with these requirements may make it more difficult and time consuming for holders of our common stock to resell their shares to third parties or to otherwise dispose of them in the market or otherwise.

We have never paid any dividends and we do not intend to pay dividends in the foreseeable future.

To date, we have not declared or paid any cash dividends on our common stock and currently intend to retain any future earnings for funding growth. We do not anticipate paying any dividends in the foreseeable future. As a result, you should not rely on an investment in our shares if you require dividend income. Capital appreciation, if any, of our shares may be your sole source of gain for the foreseeable future.

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ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable to smaller reporting companies.

ITEM 2. DESCRIPTION OF PROPERTY

On December 31, 2008, our corporate headquarters was located at 8767 E. Via de Ventura, Suite 190, Scottsdale, Arizona 85258, where we leased approximately 3,322 square feet of office space from November 1, 2007. Our minimum monthly rent expense was $7,128 plus tax per month.

On March 17, 2009, we agreed to an amendment to our two (2) year lease agreement with Bay Colony Executive Center-West, a division of BC Management Company, Inc., effective April 1, 2009 to relocate our headquarters to a 1,943 square foot suite within the Bay Colony Executive Center located at 8777 E. Via de Ventura, Suite 280, Scottsdale, Arizona 85258 and extends our current lease obligation of its office lease term to 48 months ending March 31, 2013

Our minimum monthly rent expense under the amended lease is $3,400 plus tax per month in the first year starting June 1, 2009 and will increase to $3,665 plus tax per month in the second year, $3,749 plus tax in the third year and $3,845 plus tax in the fourth year. In addition, as per the amendment, we will be charged no rent for April and May 2009. We are also responsible for our proportionate share, which is established to be 4.4%, of the direct operating and maintenance expenses of the building and real estate taxes assessed or imposed on the building. All other terms and conditions of the original lease dated October 1, 2007, as filed on Form 8-K on October 30, 2007, and all exhibits thereto shall remain in full force and effect

We believe that our facilities are adequate for our current needs and suitable additional space will be available in the future to replace existing facilities, if necessary, or to accommodate expansion of our operations. We are currently in serious arrears on the office rent and the landlord has served notice that we are in default of our lease. The Company and landlord are discussing possible remedies to this situation.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in various lawsuits and legal proceedings which arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. As of the date of this report, we are involved in an arbitration with a consultant over a disputed consulting fee of approximately $20,000. The case is scheduled to be heard by the American Arbitration Association. Other than this, we are not aware of any such legal proceedings or claims against us.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of security holders during the fourth quarter of 2010.

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PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON STOCK AND RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Common Stock

Our common stock is approved for quotation on the FINRA OTC Bulletin Board under the symbol IRBS. Our common stock is presently considered a “penny stock” and is subject to such market rules. The range of high and low bids as quoted on the OTC Bulletin Board for each quarter of 2010 and 2009 was as follows:

	2010	
	High	Low
1st Quarter	$ 0.34	$ 0.16
2nd Quarter	0.39	0.13
3rd Quarter	0.25	0.08
4th Quarter	0.10	0.05

	2009	
	High	Low
1st Quarter	$ 0.19	$ 0.02
2nd Quarter	0.40	0.15
3rd Quarter	0.54	0.15
4th Quarter	0.45	0.16

The quotations reflect inter-dealer bids without retail markup, markdown, or commission, and may not represent actual transactions. On May 13, 2011, the closing price of our common stock as reported by the OTC Bulletin Board was $0.06 per share. As of December 31, 2010, there were approximately 517 stockholders of record of our common stock.

The Company has 100,000,000 shares of voting common shares authorized for issuance. On July 10, 2008, we effected a 1-for-10 reverse stock split of our common stock and simultaneously reduced our total authorized shares of common stock to 100,000,000. As of December 31, 2010, the Company had 17,082,963 shares of common stock outstanding.

During the year ended December 31, 2010, the Company issued 2,300,849 shares of common stock as payment for consulting services. In addition, the Company issued 780,534 shares of common stock for conversion of principal of outstanding notes. The Company issued 370,723 shares as a partial payment of installment payment of principal on outstanding notes.

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In January 2009, per the term of his employment agreement, the Company issued 833,334 shares of common stock with a fair value of $250,000 to Michael K. Wilhelm, the Company's President and Chief Executive Officer. These shares were issued as a target incentive bonus for a capital raise in August 2008 and were not issued as of December 31, 2008.

In June 2009, the Company issued 66,000 shares of common stock at a price of $0.19 per share to a consultant for services.

In July 2009, the Company issued 67,332 shares of common stock at a price of $0.19 per share to a consultant for services.

In August 2009, the Company issued 66,668 shares of common stock at a price of $0.19 per share to a consultant for services.

In September 2009, the Company issued 44,444 shares of common stock at a price of $0.36 per share to a consultant for services.

In October 2009, the Company issued 44,444 shares of common stock at a price of $0.36 per share to a consultant for services.

In November 2009, the Company issued 44,444 shares of common stock at a price of $0.23 per share to a consultant for services.

In December 2009, the Company issued 200,000 shares of common stock at a price of $0.35 per share to a consultant for services.

In December 2009, per the term of a consulting contract, the Company agreed to issue 44,444 shares of common stock to a consultant. These shares were not issued as of December 31, 2009 and the fair value of these shares of $10,222 has been recorded as common stock subscribed at December 31, 2009.

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Issuance of Common Shares to Consultant

In February 2010, 500,000 shares of common stock with a fair value of $190,000 were issued to the consultant for additional services performed in November 2009 outside the scope of the original contract. The securities were issued from the Company's 2003 Stock Option, Deferred Stock, Restricted Stock and Bonus Stock Plan.

On June 1, 2009, the Company agreed to issue 200,000 shares of common stock with a fair value of $38,000 to a consultant, 66,666 shares per month beginning June 30, 2009 for services to be rendered June 1, 2009 through August 31, 2009. Per the terms of the agreement, the contract may be extended on a month-to-month basis by mutual agreement for 44,444 shares per month. In August 2009, 133,332 shares were issued for services rendered and an additional 66,668, which includes two shares issued for rounding, shares were issued in September 2009. In October 2009, the parties agreed to extend the term of the agreement by two months; therefore, the Company issued an additional 88,888 shares of common stock with a fair value of $32,000 to the consultant for services rendered from September 1, 2009 to October 31, 2009. In December 2009, the parties agreed to extend the term of the agreement by three months; therefore, the Company is to issue an additional 133,332 shares of common stock to the consultant for services rendered November 1, 2009 to January 31, 2010. In December 2009, 44,444 of these shares were issued for services performed in November 2009 with a fair value of $10,222. In April 2010, 88,888 shares were issued for services performed in December 2009 and January 2010 with a fair value of $20,444, these shares had been recorded as common stock subscribed at March 31, 2010. The securities were issued from the Company's 2003 Stock Option, Deferred Stock, Restricted Stock and Bonus Stock Plan.

On April 29, 2010, 420,000 shares of common stock with a fair value of $142,800 were issued to the consultant for additional services performed in March and April 2010 outside the scope of the original contract. The securities were issued from the Company's 2003 Stock Option, Deferred Stock, Restricted Stock and Bonus Stock Plan.

On April 27, 2010, 735,000 shares of common stock with a fair value of $227,850 were issued to a consultant for services performed in March and April 2010. The securities were issued from the Company's 2003 Stock Option, Deferred Stock, Restricted Stock and Bonus Stock Plan.

On April 29, 2010, 26,961 shares of common stock with a fair value of $9,167 were issued to a consultant for services performed in March and April 2010. The securities were issued from the Company's 2003 Stock Option, Deferred Stock, Restricted Stock and Bonus Stock Plan.

On April 29, 2010, 15,000 shares of common stock with a fair value of $5,100 were issued to a consultant for services performed in March and April 2010. The securities were issued from the Company's 2003 Stock Option, Deferred Stock, Restricted Stock and Bonus Stock Plan.

On April 29, 2010, 15,000 shares of common stock with a fair value of $5,100 were issued to an attorney for services performed in April 2010. The securities were issued from the Company's 2003 Stock Option, Deferred Stock, Restricted Stock and Bonus Stock Plan.

On May 11, 2010, 500,000 shares of common stock with a fair value of $150,000 were issued to a consultant for business development partnerships. The securities are to be issued from the Company's 2003 Stock Option, Deferred Stock, Restricted Stock and Bonus Stock Plan.

Issuance of Common Shares for Conversion of Principal to YA Global Investments, L.P.

On July 1, 2010, the Company issued to YA Global Investments, L.P. 780,534 shares of common stock for the partial conversion of principal of a $2,000,000 10% senior secured convertible debenture dated January 3, 2008, as amended,

held by YA Global. The conversion price was equal to $0.1048 per share and the fair value of the principal converted was $81,800.

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Issuance of Common Shares to YA Global Investments, L.P. for Installment Payment of Principal

On July 19, 2010 the Company and YA Global entered into an agreement to amend secured convertible debentures held by YA Global Per the agreement, the Company is required to pay a monthly installment amount of $42,000 in cash, common shares or a combination thereof to YA Global as a reduction of the outstanding debt obligation. The $42,000 monthly installment payment shall be made by converting the installment amount into shares of common stock of the Company at the lowest conversion price then available, provided volume limitations, based on the prior 20 trading days, are not exceeded and that there is not an equity conditions failure. Any amount in excess of the volume limitation must be paid in cash unless this restriction is waived for that period. The Company may, at its option following notice to the holder, redeem such installment amount in cash or by any combination of both.

On August 10, 2010 the Company issued to YA Global 59,724 shares of common stock with a fair value of $7,764 for the partial payment of the total $42,000 installment amount due for August 2010.

On September 1, 2010 the Company issued to YA Global 263,353 shares of common stock with a fair value of $34,236 for the remaining balance of the installment payment due for August 2010.

On September 8, 2010 the Company issued to YA Global 47,646 shares of common stock with a fair value of $6,194 for the partial payment of the total $42,000 installment amount due for September 2010.

Preferred Stock

On July 13, 2010 we filed a Certificate of Designation with the Secretary of State of Delaware providing for the issuance of up to 100,000 shares of a series of preferred stock for cash or exchange of other securities, rights or property and to fix and determine the designations, powers, rights, preferences, restrictions, qualifications, limitations and other matters relating to such series of preferred stock. The series of preferred stock was designated as Series A 5% Convertible Preferred Stock and the number of shares designated shall be up to 100,000. Each share of Preferred Stock shall have a par value of $.001 per share and a stated value equal to $1,000. Holders shall be entitled to receive, and the Company shall pay, cumulative dividends at the rate per share (as a percentage of the stated value per share) of 5% per annum, payable quarterly on January 1, April 1, July 1 and October 1, beginning on the first such date after the original issue date in duly authorized, validly issued, fully paid and nonassessable shares of Series A 5% Convertible Preferred Stock. The Preferred Stock shall have no voting rights. Each share of Preferred Stock shall be convertible, at any time and from time to time from and after the original issue date at the option of the holder, into that number of shares of common stock (subject to certain limitations) determined by dividing the stated value of such share of preferred stock by the conversion price of $0.30, (subject to certain adjustments).

As of December 31, 2010 we had 5,971 shares of Series A 5% Convertible Preferred Stock issued and outstanding.

Exchange of Notes Issued To Funds Managed by Brencourt Advisors, LLC For Preferred Stock

On September 15, 2010 we entered into a Securities Exchange Agreement with Brencourt Advisors, LLC to exchange notes and accrued interest totaling $5,916,667 for shares of Series A 5% Convertible Preferred Stock. The agreement, which has an effective date of July 30, 2010, exchanges: (i) secured convertible debentures, as amended, totaling $5,000,000; (ii) 0% interest convertible debentures previously issued quarterly to funds managed by Brencourt beginning December 2008 through June 30, 2010 totaling $875,000; and, (iii) accrued interest in the amount of $41,667 through July 31, 2010, for Series A 5% Convertible Preferred Stock. Pursuant to this agreement, on September 17, 2010 we issued an aggregate of 5,919 shares of Series A 5% Convertible Preferred Stock to three funds managed by Brencourt Advisors, LLC.

Issuance of Preferred Stock To Funds Managed by Brencourt Advisors, LLC For Dividend Expense

In October, 2010, we issued 52 shares of Series A Preferred Stock to funds managed by Brencourt Advisors as payment of the 5% quarterly dividend earned on September 30, 2010 and has accrued for 77 shares of Series A Preferred Stock, issued subsequentlym as the dividend earned for the quarter end December 31, 2010. The Preferred Series A shares have a stated value of $1,000 per share.

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Dividends And Distributions

We have not paid any dividends to our common stock shareholders to date, and have no plans to do so in the immediate future.

We use the services of Stalt, Inc. as our transfer agent.

Stock Options and Warrants

Options

During 2010, 65,000 options were issued to directors and officers. The options vest 50% in 30-days and the balance in twelve month equal monthly installments beginning June 2010. The Company valued these options at $14,424, of which $10,818 was charged as expense and $3,606 was unrecognized stock based compensation as of December 31, 2010. The total fair value of options vested during the three months and year ended December 31, 2010 was $1,803 and $157,381, respectively.

During 2009, 1,021,235 options were issued to consultants, advisors, directors, officers and employees. The Company estimated the fair value of the options to be $255,296 of which $108,733 was charged as expense and $146,563 was unrecognized stock based compensation as of December 31, 2009.

No options were exercised by Directors or employees in 2010 and 2009

A summary of the Company's stock option activity and related information for the years ended December 31, 2010 and 2009 is as follows:

	2010		2009	
	Options	Price Range	Options	Price Range
Outstanding Beginning of Year	2,812,403	$ 0.15-2.20	1,791,168	$ 0.15-250.00
Granted	65,000	0.27	1,021,235	0.25-250.00
Cancelled/Expired	(339,876)	-	-	-
Exercised	-	-	-	-
Outstanding End of Year	2,537,527	$ 0.15-2.20	2,812,403	$ 0.15-250.00
Exercisable End of Year	2,521,277	$ 0.15-2.20	2,309,903	$ 0.15-250.00

Options reserved for the 2003 Stock Option, Deferred Stock, Restricted Stock and Bonus Stock Plan but not issued are not included in the table above since this stock may be utilized for other purposes if not used for the plans. The weighted-average remaining contractual life of the above options is 6.5 years.

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Warrants

During 2010 and 2009, no warrants were issued.

In 2010 the Company and YA Global Investments, L.P. entered into an agreement to amend two secured convertible debentures held by YA Global dated January 3, 2008 and June 12, 2008 totaling $3,000,000 as part of the amendment, the exercise price of warrants that were issued to YA Global was reduced to a range between $0.13 and $0.45.

In 2010 the Company entered into a Securities Exchange Agreement with Brencourt Advisors, LLC to exchange notes held by Brencourt as part of the amendment the exercise price of warrants that were issued to funds managed by Brencourt was reduced to $0.30.

A summary of the Company's stock warrant activity and related information for the years ended December 31, 2010 and 2009 is as follows:

	2010		2009	
	Warrants	Price Range	Warrants	Price Range
Outstanding Beginning of Year	5,927,435	$ 0.13-5.00	7,020,975	$ 1.25-5.00
Granted	-	-	-	-
Cancelled/Expired	(14,331)	2.40	(1,093,540)	0.50-10.00
Exercised	-	-	-	-
Outstanding End of Year	5,913,104	$ 0.13-5.00	5,927,435	$ 1.25-5.00
Exercisable End of Year	5,913,104	$ 0.13-5.00	5,927,435	$ 1.25-5.00

The weighted-average remaining contractual life of the warrants outstanding at December 31, 2010 is 2.13 years.

Notes Payable

As of December 31, 2010 we have $3,613,895 in notes payable, of which $3,613,895 is current on December 31, 2010.

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In 2010 the Company and YA Global Investments, L.P. entered into an agreement to amend two secured convertible debentures held by YA Global dated January 3, 2008 and June 12, 2008 in the amount of $2,000,000 and $1,000,000, respectively. The debentures per the agreement are amended to: (i) extend the maturity dates to December 31, 2011; (ii) increase the annual interest rate from ten percent (10.0%) to thirteen percent (13.0%); (iii) eliminate the $1,500,000 optional redemption provision; (iv) reduce the conversion price of the debentures to a range between $0.13 and $0.45; and, (v) require the Company pay a monthly installment amount of $42,000 in cash, stock or a combination thereof to YA Global as a reduction of the outstanding debt obligation.

Per the agreement, the conversion price of the $2,000,000 note prior to the occurrence of any triggering event, will be $0.13 for the first $1,500,000 converted and $0.17 for the remaining $500,000 converted. The conversion price of the $1,000,000 note prior to the occurrence of any triggering event has been reduced to be $0.17 for the first $500,000 converted and $0.22 for the remaining $500,000 converted. For both notes, following the occurrence of any triggering event, the conversion price shall be eighty percent (80%) of the lowest daily volume weighted average price for the thirty (30) trading days immediately prior to the applicable conversion date.

With regard to the $42,000 monthly installment payment, the Company shall pay to the holder by converting the installment amount into shares of common stock of the Company at the lowest conversion price then available, provided that there is not an equity conditions failure and volume limitations, based on the prior 20 trading days, allow. Any amount in excess of the volume limitation must be paid in cash unless this restriction is waived for that period. The Company may, at its option following notice to the holder, redeem such installment amount in cash or by any combination of both. Further, so long as no event of default has occurred and is continuing and the Company has paid to the holder all prior installment amounts, the Holder agrees to not convert any portion of this debenture during the calendar month immediately following the applicable installment date.

Furthermore, on July 19, 2010 the Company and YA Global entered into an agreement to amend, restate and consolidate into one debenture all 0% interest convertible debentures previously issued quarterly to YA Global beginning September 30, 2008 through June 30, 2010. The total principal due under the secured convertible note is $593,888.84 with an annual interest rate of 13.0% and maturing on December 31, 2011. The conversion price of the note prior to the occurrence of any triggering event, will be $0.25 for the first $143,888.54 converted, $0.30 for the next $75,000.00 converted, $0.35 for the following $75,000.00 converted and $0.45 for the remaining $300,000.30 converted. Following the occurrence of any triggering event, the conversion price shall be eighty percent (80%) of the lowest daily volume weighted average price for the thirty (30) trading days immediately prior to the applicable conversion date.

In 2010, the Company paid $129,994 of principal of the $2,000,000 note held by YA Global.

In 2010 the Company entered into a Securities Exchange Agreement with Brencourt Advisors, LLC to exchange notes held by Brencourt totaling $5,875,000 and $41,667 of accrued interest for shares of Series A Convertible Preferred Stock. The agreement, which has an effective date of July 30, 2010, exchanges: (i) Secured Convertible Debentures, as amended totaling $5,000,000; (ii) 0% interest convertible debentures previously issued quarterly to funds managed by Brencourt beginning December 2008 through June 30, 2010 totaling $875,000; and, (iii) accrued interest in the amount of $41,667 through July 31, 2010, for Series A Convertible Preferred Stock.

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Series A Promissory Notes Issued To Investors

In October and November, 2010 the Company issued a series of unsecured promissory notes to a group of accredited investors in the aggregate principal amount of $150,000. The notes mature in 90 days and bear simple interest at a rate of 25% per annum.

As of December 31, 2010 and December 31, 2009 notes payable consist of:

	December 31, 2010	December 31, 2009
YA Global Investments, L.P. Debentures	$ 2,870,006	$ 3,000,000
Note Issued To YA Global Investments, L.P. For Accrued Interest	593,889	443,889
Brencourt Advisors, LLC Debentures	-	5,000,000
Note Issued To Brencourt Advisors, LLC For Accrued Interest	-	625,000
Series A Notes Issued To Investors	150,000	-
Less: Debt discount	-	(3,006,498)
Total note payable	3,613,895	6,062,391
Less: current portion of notes payable	(3,613,895)	2,000,000
Total long term portion of notes payable	$ -	$ 4,062,391

Aggregate maturities of notes payable as of December 31, 2010 are as follows:

For the twelve months ended December 31,	Amount
2011	$ 3,613,895
2012	-
2013	-
2014	-
2015	-
	$ 3,613,895

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UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Convertible Debentures Sold For Accrued Interest

On March 31, 2009, per the terms of the amended Securities Purchase Agreement with YA Global Investments, L.P., the Company issued two 0% interest convertible debentures with a five year term of exercise and a minimum conversion price of $0.30 per share as payment of an aggregate of $75,000 in interest accrued during the three months ended March 31, 2009. The securities were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On March 31, 2009, per the terms of the amended Securities Purchase Agreement with Funds Managed by Brencourt Advisors, LLC the Company issued four 0% interest convertible debentures with a five year term of exercise and a minimum conversion price of $0.30 per share as payment of an aggregate of $125,000 in interest accrued during the three months ended March 31, 2009. The securities were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On June 30, 2009, per the terms of the amended Securities Purchase Agreement with YA Global, the Company issued two 0% interest convertible debentures with a five year term of exercise and a minimum conversion price of $0.30 per share as payment of an aggregate of $75,000 in interest accrued during the three months ended June 30, 2009. The securities were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On June 30, 2009, per the terms of the amended Securities Purchase Agreement with Funds Managed by Brencourt Advisors, LLC the Company issued four 0% interest convertible debentures with a five year term of exercise and a minimum conversion price of $0.30 per share as payment of an aggregate of $125,000 in interest accrued during the three months ended June 30, 2009. The securities were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On September 30, 2009, per the terms of the amended Securities Purchase Agreement with YA Global, the Company issued two 0% interest convertible debentures with a five year term of exercise and a conversion price of $0.34 per share, subject to adjustment, as payment of an aggregate of $75,000 in interest accrued during the three months ended September 30, 2009. The securities were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On September 30, 2009, per the terms of the amended Securities Purchase Agreement with Funds Managed by Brencourt Advisors, LLC the Company issued four 0% interest convertible debentures with a five year term of exercise and a conversion price of $0.34 per share, subject to adjustment, as payment of an aggregate of $125,000 in interest accrued during the three months ended September 30, 2009. The securities were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On December 31, 2009, per the terms of the amended Securities Purchase Agreement with YA Global, the Company issued two 0% interest convertible debentures with a five year term of exercise and a minimum conversion price of $0.30 per share as payment of an aggregate of $75,000 in interest accrued during the three months ended December 31, 2009. The securities were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On December 31, 2009, per the terms of the amended Securities Purchase Agreement with Funds Managed by Brencourt Advisors, LLC the Company issued four 0% interest convertible debentures with a five year term of

exercise and a minimum conversion price of $0.30 per share as payment of an aggregate of $125,000 in interest accrued during the three months ended December 31, 2009. The securities were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

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Sale of Series A 5% Convertible Preferred Stock

On September 15, 2010 the Company entered into a Securities Exchange Agreement with Brencourt Advisors, LLC to exchange notes and accrued interest totaling $5,916,667 for shares of Series A 5% Convertible Preferred Stock. The agreement, which has an effective date of July 30, 2010, exchanges: (i) secured convertible debentures, as amended, totaling $5,000,000; (ii) 0% interest convertible debentures previously issued quarterly to funds managed by Brencourt beginning December 2008 through June 30, 2010 totaling $875,000; and, (iii) accrued interest in the amount of $41,667 through July 31, 2010, for Series A 5% Convertible Preferred Stock. Pursuant to this agreement, on September 17, 2010 the Company issued an aggregate of 5,919 shares of Series A 5% Convertible Preferred Stock to three funds managed by Brencourt Advisors, LLC. The securities were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

Issuance of Preferred Stock To Funds Managed by Brencourt Advisors, LLC For Dividend Expense

In October, 2010, the Company issued 52 shares of Series A Preferred Stock to funds managed by Brencourt Advisors as payment of the 5% quarterly dividend earned on September 30, 2010 and has accrued for 77 shares of Series A Preferred Stock, issued subsequently, as the dividend earned for the quarter end December 31, 2010. The Preferred Series A shares have a stated value of $1,000 per share. The securities were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

EQUITY COMPENSATION PLANS

Refer to Item 11 below for information with respect to our equity compensation plans.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

Not applicable to smaller reporting companies.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

The following discussion of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and the related notes that are included in this Report.

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Some of the statements contained in this "Management's Discussion and Analysis of Financial Condition and Results of Operation" and elsewhere in this Report are forward-looking statements that involve substantial risks and uncertainties. All statements other than historical facts contained in this report, including statements regarding our future financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "believes," "expects," "anticipates," "intends," "estimates," "may," "will," "continue," "should," "plan," "predict," "potential" and other similar expr have based these forward-looking statements on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. Our actual results could differ materially from those anticipated in these forward-looking statements, which are subject to a number of risks, uncertainties and assumptions described in the "Risk Factors" section and elsewhere in this report.

Company History

We were originally incorporated in the State of Delaware in June 1985 under the name Vocaltech, Inc. to develop, design, manufacture and market products utilizing proprietary speech-generated tactile feedback devices. We completed our initial public offering of our securities in October 1987. In January 1992, we effected a 1-for-6.3 reverse stock split of our common stock. We changed our name to InnoTek, Inc. in November 1992. In December 1994, we acquired all of the outstanding stock of InnoVisions, Inc., a developer and marketer of skin protective products, discontinued our prior operations in their entirety and changed our name to DermaRx Corporation. In April 2000, we effected a reverse merger with a subsidiary of Go Public Network, Inc., which was engaged in assisting early-stage development and emerging growth companies with financial and business development services. We changed our name to GoPublicNow.com, Inc., effected a 1-for-5 reverse stock split and discontinued our prior operations in their entirety. In November 2000, we changed our name to GPN Network, Inc. In July 2001, we discontinued the operations of GPN Network, Inc. in their entirety and began looking for appropriate merger partners. Our objective became the acquisition of an operating company with the potential for growth in exchange for our securities. In July 2003, we effected a reverse merger with ImmuneRegen BioSciences, Inc., adopted our current business model and thereafter changed our name to IR BioSciences Holdings, Inc. In July 2003, we effected a 1-for-20 reverse stock split, and in April 2004, we effected a 2-for-1 stock split. In June 2006, our stockholders voted to increase the number of authorized shares of Common Stock to 250,000,000. On August 1, 2008, the Company effected a 1-for-10 reverse stock split of all of its issued and outstanding shares of common stock and simultaneously reduced its authorized shares of common stock to 100,000,000; par value remained unchanged. Accordingly, the number of shares and per share amounts included in the consolidated financial statements and the accompanying notes included in the F- section have been adjusted to reflect the Reverse Stock Split retroactively. Unless otherwise indicated, all references to number of share, per share amounts and earnings per share information contained in this report give effect to the 1-for-10 reverse stock split.

ImmuneRegen BioSciences, Inc. was incorporated in October 2002; all information contained herein refers to the operations of ImmuneRegen BioSciences, Inc., our wholly-owned operational subsidiary.

Overview

While our research and development activities have discontinued due to lack of capital, we continue to seek out-licensing arrangements and collaborations with partners to complete development and achieve commercialization. We have not commenced any product commercialization and, until such time, we will not generate significant product revenues. Our accumulated deficit has increased, from $27,759,973 at December 31, 2009 to $33,038,117 at December 31, 2010. Operating losses are expected to continue for the foreseeable future and until such time as the Company is able obtain a pharmaceutical partner or attain sales levels sufficient to support operations.

In 2011, if proper funding can be obtained, we will continue research and development activities, as well as the activities necessary to develop commercial partnerships and licenses. Expenditure of financial resources in 2011 will fall principally into five broad categories, as follows: Research and Development; Personnel; Consulting and Professional (except legal and accounting); Legal and Accounting; and Public Relations, Investor Relations and Shareholder Relations.

The preliminary results of our pre-clinical studies may not be indicative of results that will be obtained from subsequent studies or from more extensive trials. Further, our pre-clinical or clinical trials may not be successful, and we may not be able to obtain the required regulatory approvals in a timely fashion, or at all. See "Risk Factors."

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Liquidity and Capital Resources

At December 31, 2010, we had current assets of $44,930 consisting of cash and cash equivalents of $0, and prepaid assets and other current assets of $44,930. Also, at December 31, 2010, we had current liabilities of $6,506,945, consisting of accounts payable and accrued liabilities of $2,568,903, notes payable of $3,613,895 and a redemption option liability of $300,000. This resulted in a working capital deficit of $6,462,015. During the twelve months ended December 31, 2010, we used cash in operating activities of $430,309. From the date of inception (October 30, 2002) to December 31, 2010, we had a net loss of $33,038,117 and used cash of $16,526,202 in operating activities. We met our cash requirements from our inception (October 30, 2002) through December 31, 2010 via the private placement of $7,889,151 of our common stock and $8,723,628 from the issuance of notes payable, net of repayments. Continued losses and lack of liquidity indicate that we may not be able to continue as a going concern for a reasonable period of time. The ability to continue as a going concern is dependent upon several factors including, but not limited to, the ability to generate sufficient cash flow to meet obligations on a timely basis, obtain additional financing and continue to obtain supplies and services from vendors.

We currently have no revenue. There is no guarantee that our business model will be successful, or that we will be able to generate sufficient revenue to fund future operations. As a result, we expect our operations to continue to use net cash, and that we will be required to seek additional debt or equity financings during the coming quarters. Since inception, we have financed our operations through debt and equity financing. While we have raised capital to meet our working capital and financing needs in the past, additional financing is required in order to meet our current and projected cash flow deficits from operations and development of our product line.

We will need to raise additional funds in order to fully execute our 2011 Plan. We are presently negotiating with human and animal health commercial development partners in various regions of the world. We believe that one or more of these agreements will be executed during 2011. These agreements could generally include provisions for the commercial partner to pay us a technology access fee, could include payments for a portion of the clinical trial expenses, could include payment obligations to us upon the accomplishment of certain defined tasks and/or could provide for payments relating to the future sales of commercial product. These agreements could be an important source of funds. However, there can be no assurance that we will be successful in obtaining additional funding from human health commercial development partners, institutional or private investors. If we are not successful in raising additional funds, we may be forced to cease operations.

Total outstanding current liabilities were approximately $3,421,444 (111%) higher at the end of 2010 with approximately $6,506,945 at December 31, 2010, as compared to approximately $3,085,501 at December 31, 2009. Contributing to this increase were approximately $1,500,000 of the long term debentures reaching maturity due and an increase in accrued liabilities.

In July 2008, we received a total of $11,250 from the exercise of an aggregate of 30,000 common stock purchase warrants of common stock at $0.375 per share by five investors.

In December 2006, we completed a private placement, whereby we sold an aggregate of $5,482,600 worth of units, consisting of shares of common stock and warrants, to accredited investors. In consideration of the investment, we granted to each investor certain registration rights and anti-dilution rights. We agreed that not before 180 days after the closing of the private placement and not later than 190 days thereafter, that we would file with the SEC an appropriate registration statement to register these shares along with the shares underlying the warrants. In the event that we failed to comply with the filing deadline, there was a 1% penalty for each 30 day period (or pro rata portion thereof) paid to each investor in cash or additional shares. This penalty amounts to an aggregate of 342,662 shares and 171,331 warrants per 30 day period until such a time as a registration statement that includes these shares and warrants is filed or 12 months. Because we complied with the filing deadline, as of December 31, 2008, we are not

subject to any penalty.

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Since our inception, we have been seeking additional third-party funding. During such time, we have retained a number of different investment banking firms to assist us in locating available funding; however, we have not yet been successful in obtaining any of the long-term funding needed to make us into a commercially viable entity. During the period from October 2002 to December 31, 2008, we were able to obtain financing of $17,557,526 from the private placements of our securities (which resulted in net proceeds to us of $16,462,779). In January 2008 we sold $2 million in secured convertible debentures which resulted in net proceeds to us of $1,815,000. In June 2008 we sold an additional $1 million of the secured convertible debentures as per the terms of the securities purchase agreement with YA Global Investments L.P. In August 2008 we sold $5 million in secured convertible debentures to a group of funds managed by Brencourt Advisors LLP. We currently need additional financing to fund our immediate operating expenses. If we are not successful in generating sufficient liquidity from operations or in raising sufficient capital resources, it would have a material adverse effect on our business, results of operations, liquidity and financial condition.

While we have raised capital to meet our working capital and financing needs in the past through debt and equity financings, additional financing will be required in order to implement our business plan and to meet our current and projected cash flow deficits from operations and development. There can be no assurance that we will be able to consummate future debt or equity financings in a timely manner on a basis favorable to us, or at all. If we are unable to raise needed funds, we will not be able to develop or enhance our potential products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets ,seeking an acquisition partner or ceasing operations.

During fiscal year 2011, we will pay, or accrue pay if funding is not secured, our Chief Executive Officer, Chief Financial Officer and Chief Scientific Officer an aggregate of $775,000 pursuant to their employment agreements.

As of December 31, 2010 we have $3,613,895 in notes payable, all of which is current on December 31, 2010.

Until such time, if at all, as we receive adequate funding, we intend to continue to defer payment of all of our obligations which are capable of being deferred, which actions have resulted in some vendors demanding cash payment for their goods and services in advance, and other vendors refusing to continue to do business with us. We do not expect to generate a positive cash flow from our operations for at least several years, if at all, due to anticipated expenditures for research and development activities, administrative and marketing activities, and working capital requirements and expect to continue to attempt to raise further capital through one or more further private placements. We believe that we will require an additional $3,500,000 to meet our expenses over the next 12 months.

Critical Accounting Policies

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and judgments that affect our reported assets, liabilities, revenues, and expenses, and the disclosure of contingent assets and liabilities.

We base our estimates and judgments on historical experience and on various other assumptions we believe to be reasonable under the circumstances. Future events, however, may differ markedly from our current expectations and assumptions. While there are a number of significant accounting policies affecting our consolidated financial statements; we believe the following critical accounting policy involves the most complex, difficult and subjective estimates and judgments:

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Stock-based Compensation

The Company accounts for our stock based awards in accordance with Accounting Standards Codification subtopic 718-10, Compensation ("ASC 718-10")., which requires a fair value measurement and recognition of compensation expense for all share-based payment awards made to our employees and directors, including employee stock options and restricted stock awards.

The Company estimates the fair value of stock options granted using the Black-Scholes valuation model. This model requires us to make estimates and assumptions including, among other things, estimates regarding the length of time an employee will retain vested stock options before exercising them, the estimated volatility of our common stock price and the number of options that will be forfeited prior to vesting. The fair value is then amortized on a straight-line basis over the requisite service periods of the awards, which is generally the vesting period. Changes in these estimates and assumptions can materially affect the determination of the fair value of stock-based compensation and consequently, the related amount recognized in our consolidated statements of operations.

The expected term of the options represents the estimated period of time until exercise and is based on historical experience of similar awards, giving consideration to the contractual terms, vesting schedules and expectations of future employee behavior.

Recent Accounting Pronouncements

For a discussion of new accounting pronouncements affecting the Company, refer to Note 1 of Notes to Financial Statements.

Result of Operations

Comparison of results for the fiscal year ended December 31, 2010, to the fiscal year ended December 31, 2009.

Revenues

We have not generated any revenues from operations from our inception.

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Costs and Expenses

From our inception (October 30, 2002) through December 31, 2010, we have incurred losses of $33,038,117. These expenses were associated principally with equity-based compensation to employees and consultants, product development costs and professional services, interest expense and equity based compensation to stockholders for the penalty incurred for the late registration of shares.

Selling, General and Administrative Expenses

Selling, General and Administrative expenses were reduced from $3,126,423 for the fiscal year ended December 31, 2009 to $2,859,576 for the fiscal year ended December 31, 2010, a cost savings of $ 266,847 or approximately 9%. This was mostly because payroll and related expenses were cut by $75,004 (7.6%) from $987,117 in 2009 to $912,113 in 2010, research and development cost were reduced by 289,882(51.9%), legal and accounting fees were reduced by $267,367 (44.3%), and consulting and professional fees were reduced by $149,044 (55.0%). These reductions were somewhat offset by non-cash compensation which increased by $666,199 (287.9%).

Interest Expense

For the twelve months ending December 31, 2010, Interest Expense (net) was $1,706,502 a decrease of approximately 21% compared to Interest Expense (net) of $2,163,065 during the 12 months ended December 31, 2009.

Net Loss

Our net loss for the twelve months ending December 31, 2010 was $5,278,144 or $0.34 per share versus a net loss for the twelve months ending December 31, 2009 of $6,462,817 or $0.49 per share. For the period of inception (October 30, 2002) through December 31, 2010, our net loss was $33,037,117, or $3.77 per share. In addition to the year over year variances described above, the net loss was primarily due to a loss in the twelve month period ending December 31, 2010 on the extinguishment of debt in the amount of $5,431,861 that was partially offset by a gain of $4,738,450 due to the change in value of the equity-linked financial instruments as mandated by ASC Accounting for Derivative Instruments and Hedging. (See Note 6 of the Notes to consolidated financial statements, December 31, 2010 – Derivative Liabilities).

We expect that losses will continue at least through the year ending December 31, 2011.

Acquisition or Disposition of Plant and Equipment

We did not acquire any property, plant or equipment for the year ended December 31, 2010. We do not anticipate the acquisition or disposition of any significant property, plant or equipment during the next 12 months.

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ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable to a smaller reporting company.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements of the Company are set forth beginning on page F-1 immediately following the signature page of this report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our principal executive and financial officers, as appropriate to allow timely decisions regarding required disclosure.

As of the end of the period covered by this Annual Report on form 10-K, our management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial (and principal accounting) Officer, carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Exchange Act). Based upon that evaluation and due to the material weakness existing in our internal controls as of December 31, 2010, we have concluded our disclosure controls and procedures were ineffective.

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Changes in internal controls.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. Material weaknesses would permit information required to be disclosed by the Company in the reports that it files or submits to not be recorded, processed, summarized and reported, within the time periods specified in the Securities Exchange Commission's rules and forms. In our Amendment No. 1 to our Annual Report on Form 10-KSB/A for the year ended December 31, 2007, we identified a material weakness consisting of limited resources and a limited number of employees, namely the lack of an audit committee, an understaffed financial and accounting function, and the need for additional personnel to prepare and analyze financial information in a timely manner and to allow review and on-going monitoring and enhancement of our controls.

We have taken various steps to remediate the deficiencies that gave rise to this material weakness. We formed an audit committee in June 2008 and in the fourth quarter of 2008, we provided additional education to our employees regarding our code of ethics, standard operating procedures, stock trading policy and our whistle blower hotline. In 2009, we took measures, including evaluating and improving our existing internal control documentation and procedures to develop clear identification of key financial and reporting controls and using an external consultant to review our control procedures to assure compliance and enhancement, as needed, to existing controls, to remediate the material weakness. During 2010 we continued to evaluate our internal control documentation. We are unable to conclude that the material weakness described above was remediated as of December 31, 2010. As a result, we have concluded our internal controls were ineffective as of December 31, 2010.

There were no other changes in our internal controls over financial reporting during the year ended December 31, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include, but are not limited to, the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

ITEM 9B. OTHER INFORMATION

None.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item 10 is incorporated by reference from our definitive proxy statement on Schedule 14A which will be filed before the end of the 120-day period immediately following the end of our 2010 fiscal year, or, if our definitive proxy statement is not filed within that time, the information will be filed as part of an amendment to this Annual Report on Form 10-K/A, not later than the end of the 120-day period.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is incorporated by reference from our definitive proxy statement on Schedule 14A which will be filed before the end of the 120-day period immediately following the end of our 2010 fiscal year, or, if our definitive proxy statement is not filed within that time, the information will be filed as part of an amendment to this Annual Report on Form 10-K/A, not later than the end of the 120-day period.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item 12 is incorporated by reference from our definitive proxy statement on Schedule 14A which will be filed before the end of the 120-day period immediately following the end of our 2010 fiscal year, or, if our definitive proxy statement is not filed within that time, the information will be filed as part of an amendment to this Annual Report on Form 10-K/A, not later than the end of the 120-day period.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item 13 is incorporated by reference from our definitive proxy statement on Schedule 14A, or, if our definitive proxy statement is not filed within that time, the information will be filed as part of an amendment to this Annual Report on Form 10-K/A, not later than the end of the 120-day period.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item 14 is incorporated by reference from our definitive proxy statement on Schedule 14A, or, if our definitive proxy statement is not filed within that time, the information will be filed as part of an amendment to this Annual Report on Form 10-K/A, not later than the end of the 120-day period.

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Exhibit Number	Description of Exhibit
2.1	Agreement and Plan of Merger dated July 2, 2003 among the Registrant, GPN Acquisition Corporation and ImmuneRegen BioSciences, Inc. (incorporated by reference to exhibit 2 of the Registrant's current report on Form 8-k filed with the Securities and Exchange Commission on July 7, 2003).
3.1	Certificate of Incorporation filed with the Delaware Secretary of State on June 4, 1985 (incorporated by reference to exhibit 3.1 of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(a)	Certificate of Amendment filed with the Delaware Secretary of State on July 16, 1987 (incorporated by reference to exhibit 3.1(a) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(b)	Certificate of Amendment filed with the Delaware Secretary of State on February 3, 1992 (incorporated by reference to exhibit 3.1(b) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(c)	Certificate of Amendment filed with the Delaware Secretary of State on November 23, 1992 (incorporated by reference to exhibit 3.1(c) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(d)	Certificate of Amendment filed with the Delaware Secretary of State on December 15, 1994 (incorporated by reference to exhibit 3.1(d) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(e)	Certificate of Amendment filed with the Delaware Secretary of State on November 7, 1995 (incorporated by reference to exhibit 3.1(e) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(f)	

	Certificate of Amendment filed with the Delaware Secretary of State on December 30, 1996 (incorporated by reference to exhibit 3.1(f) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(g)	Certificate of Amendment filed with the Delaware Secretary of State on November 8, 2000 (incorporated by reference to exhibit 3.1(h) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(h)	Certificate of Amendment filed with the Delaware Secretary of State on June 27, 2008.
3.1(i)	Certificate of Amendment filed with the Delaware Secretary of State on July 10, 2008.
3.2	Amended and Restated Bylaws of the Registrant dated as of January 1, 2002 (incorporated by reference to exhibit 3(b) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
4.1	Specimen Common Stock Certificate (incorporated by reference to exhibit 4.1 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).
4.2	2003 Stock Option, Deferred Stock and Restricted Stock Plan (incorporated by reference to exhibit 4.1 of the Registrant's registration statement on Form S-8 (file no. 333-113511) filed with the Securities and Exchange Commission on March 11, 2004).

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Exhibit Number	Description of Exhibit
4.3	Amendment No. 1 to IR BioSciences Holdings, Inc. 2003 Stock Option, Deferred Stock and Restricted Stock Plan (incorporated by reference to Annex B to the definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on June 5, 2006).
4.4	Amendment No. 2 (titled “Amendment No. 3”) to IR BioSciences Holdings, Inc. 2003 Stock Option, Deferred Stock and Restricted Stock Plan (incorporated by reference to Appendix B to the definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on May 9, 2008).
4.5	Form of Warrant by and between the Registrant and each of the Investors or Creditors, as the case may be, who entered into an Agreement filed as Exhibit 10.6, 10.7, 10.8 or 10.9 herewith (incorporated by reference to exhibit 4.1 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2004).
4.6	Form of Registration Rights (Annex A to Subscription Agreement) by and between the Registrant and each of the Investors who entered into the Agreements filed as Exhibits 10.6 and 10.8 herewith (incorporated by reference to exhibit 4.2 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2004).
4.7	Form of Anti-Dilution Rights (Annex B to Subscription Agreement) by and between the Registrant and each of the Investors who entered into the Agreements filed as Exhibits 10.6 and 10.8 herewith (incorporated by reference to exhibit 4.3 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2004).
4.8	Promissory Note issued from the Registrant to SBM Certificate Company as of April 28, 2004 (incorporated by reference to exhibit 4.6 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).
4.8	Form of Warrant by and between the Registrant and each of the investors who entered into the Subscription Agreements filed as Exhibits 10.18, 10.19 and 10.20 herewith (incorporated by reference from Exhibit 4.1 to the Quarterly Report on Form 10-QSB as filed with the Securities and Exchange Commission on November 14, 2006).
4.10	8% Secured Convertible Debenture due December 31, 2010, issued to YA Global Investments, L.P., dated January 3, 2008 (incorporated by reference from Exhibit 4.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 9, 2008).

4.11	Common Stock Purchase Warrant, issued to YA Global Investments, L.P., dated January 3, 2008 (incorporated by reference from Exhibit 4.2 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 9, 2008).
4.12	8% Secured Convertible Debenture due May 31, 2011 in the amount of $1,000,000, issued to YA Global Investments, L.P., dated June 12, 2008 (incorporated by reference from Exhibit 4.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on June 17, 2008)
4.13	Amendment Number 1 to 8% Secured Convertible Debenture in the amounts of $2,000,000 and $1,000,000, issued to YA Global Investments, L.P., dated January 3, 2008 and June 12, 2008, respectively (incorporated by reference from Exhibit 4.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 23, 2008).
4.14	Waiver of Application of Provisions Under Secured Convertible Debenture between the Company and YA Global Investments, L.P. dated July 18, 2008 (incorporated by reference from Exhibit 4.2 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on July 23, 2008).
4.15	Form of 10% Secured Convertible Debenture due August 8, 2013 dated August 8, 2008 issued to Funds Managed by Brencourt Advisors LLC (incorporated by reference from Exhibit 4.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 11, 2008).
4.16	Form of Common Stock Purchase Warrant dated August 8, 2008 issued to Funds Managed by Brencourt Advisors LLC (incorporated by reference from Exhibit 4.2 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 11, 2008)

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Exhibit Number	Description of Exhibit
4.17	Amendment Number 2 to 8% Secured Convertible Debenture in the amount of $2,000,000 issued to YA Global Investments, L.P., dated January 3, 2008 (incorporated by reference from Exhibit 4.3 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 11, 2008).
4.18	Amendment Number 2 to 8% Secured Convertible Debenture in the amount of $1,000,000 issued to YA Global Investments, L.P., dated June 12, 2008 (incorporated by reference from Exhibit 4.4 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 11, 2008)
4.19	Amendment Number 1 to Common Stock Purchase Warrant, issued to YA Global Investments, L.P., dated August 8, 2008 (incorporated by reference from Exhibit 4.5 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 11, 2008)
4.20	Common Stock Purchase Warrant, issued to YA Global Investments, L.P., dated August 8, 2008 incorporated by reference from Exhibit 4.6 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 11, 2008).
10.1	License Agreement dated December 16, 2002 among ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, David Harris and Mark Witten (incorporated by reference to exhibit 10.4 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).
10.1(a)	First Amendment to License Agreement dated December 20, 2002 among ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, David Harris and Mark Witten (incorporated by reference to exhibit 10.4(a) of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).
10.1(b)	Second Amendment to License Agreement dated June 26, 2003 among ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, David Harris and Mark Witten (incorporated by reference to exhibit 10.4(b) of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).
10.1(c)	Assignment Agreement dated February 23, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Mark Witten (incorporated by reference to exhibit 10.4(c) of the Registrant's

registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on July 20, 2005).

10.1(d) Assignment Agreement dated February 23, 2005 among ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, David Harris and Mark Witten (incorporated by reference to exhibit 10.4(d) of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on July 20, 2005).

10.1(e) Assignment Agreement dated November 7, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Mark Witten (incorporated by reference to exhibit 10.4(e) of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 16, 2005).

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Exhibit Number	Description of Exhibit
10.1(f)	Assignment Agreement dated November 7, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Mark Witten (incorporated by reference to exhibit 10.4(f) of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).
10.1(g)	Assignment Agreement dated November 7, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Mark Witten (incorporated by reference to exhibit 10.4(g) of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 16, 2005).
10.1(h)	Assignment Agreement dated November 7, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Mark Witten (incorporated by reference to exhibit 10.4(h) of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 16, 2005).
10.2	Lease Agreement dated July 1, 2004 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, and The Clayton Companies (incorporated by reference to exhibit 10.5 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).
10.3	Form of Subscription Agreement entered into as of October 13, 2004 between the Registrant and each of the Investors set forth on the Schedule of Investors thereto (incorporated by reference to exhibit 10.1 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2004).
10.4	Form of Settlement Agreement entered into as of October 13, 2004 between the Registrant and each of the Creditors set forth on the Schedule of Creditors thereto (incorporated by reference to exhibit 10.2 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2004).
10.5	Form of Subscription Agreement entered into as of October 26, 2004 between the Registrant and each of the Investors set forth on the Schedule of Investors thereto (incorporated by reference to exhibit 10.1 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 27, 2004).

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Exhibit Number	Description of Exhibit
10.6	Form of Settlement Agreement entered into as of October 26, 2004 between the Registrant and each of the Creditors set forth on the Schedule of Creditors thereto (incorporated by reference to exhibit 10.2 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 27, 2004).
10.7	Employment Agreement dated August 10, 2005 by and between the Registrant and Michael K. Wilhelm (incorporated by reference to exhibit 10.1 of the Registrant's quarterly report on Form 10-QSB for the three months ended September 30, 2005).
10.8	Change of Control Agreement dated August 10, 2005 by and between the Registrant and Michael K. Wilhelm (incorporated by reference to exhibit 10.2 of the Registrant's quarterly report on Form 10-QSB for the three months ended September 30, 2005).
10.9	Severance Agreement dated November 7, 2005 by and between the Registrant and Michael K. Wilhelm (incorporated by reference to exhibit 10.3 of the Registrant's quarterly report on Form 10-QSB for the three months ended September 30, 2005).
10.10	Authorization for Regulatory Contact dated November 7, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, and Synergos, Inc. (incorporated by reference to exhibit 10.14 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).
10.11	Proforma invoice/quotation dated November 7, 2005 from Sigma-Aldrich, Inc. to ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant (incorporated by reference to exhibit 10.15 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 16, 2005).
10.12	Letter of acceptance dated October 2, 2003, from Huntingdon Life Sciences to ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant (incorporated by reference to exhibit 10.16 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).
10.13	Price Quotation dated June 27, 2003 received by ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant from AppTec Laboratory Services (incorporated by reference to exhibit 10.17 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).

10.14	Consulting Agreement dated March 15, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Dr. Hal Siegel, Ph.D. (Siegel Consultancy) (incorporated by reference to exhibit 10.18 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).

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Exhibit Number	Description of Exhibit
10.15	Consulting Agreement dated November 3, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Dr. Jack Caravelli, Ph.D (incorporated by reference to exhibit 10.19 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).
10.16	Consulting Agreement dated July 29, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Dr. Kelly McQueen, MD, MPH (incorporated by reference to exhibit 10.20 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).
10.17	Form of Subscription Agreement entered into as of December 6, 2006 between the Registrant and each of the Investors set forth on the Schedule of Investors contained therein (incorporated by reference from Exhibit 10.1 to the Report on Form 8-K as filed with the Securities and Exchange Commission on December 7, 2006).
10.18	Form of Subscription Agreement entered into as of October 4, 2006 between the Registrant and each of the Investors set forth on the Schedule of Investors contained therein. (incorporated by reference from Exhibit 10.2 to the Quarterly Report on Form 10-QSB as filed with the Securities and Exchange Commission on November 14, 2006).
10.19	Form of Subscription Agreement entered into as of October 26, 2006 between the Registrant and each of the Investors set forth on the Schedule of Investors contained therein (incorporated by reference from Exhibit 10.2 to the Quarterly Report on Form 10-QSB as filed with the Securities and Exchange Commission on November 14, 2006).
10.20	Standard Form of Director Indemnification Agreement (incorporated by reference from Exhibit 10.21 to the Annual Report on Form 10-KSB/A as filed with the Securities and Exchange Commission on April 30, 2007).
10.21	Agreement dated May 14, 2007 by and between the Company and Dr. Lance K. Gordon (incorporated by reference from Exhibit 10.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on May 17, 2007).
10.22	Agreement dated August 14, 2007 by and between the Company and Dr. Robert J. Hariri Gordon (incorporated by reference from Exhibit 10.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 17, 2007).
10.23	

Office Lease dated October 25, 2007 by and between the Company and Bay Colony Executive Center-West, a division of BC Management Company, Inc. (incorporated by reference from Exhibit 10.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on October 30, 2007).

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Exhibit Number	Description of Exhibit
10.24	Amendment for an Extension to Lease Term and to Relocate to Suite 280 at the Bay Colony Executive Center - East dated March 17, 2009 by and between the Company and Bay Colony Executive Center-West, a division of BC Management Company, Inc. (incorporated by reference from Exhibit 10.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 20, 2009).
10.25	Securities Purchase Agreement, dated as of January 3, 2008, by and among the Company, YA Global Investments, L.P., and ImmuneRegen BioSciences, Inc. (incorporated by reference from Exhibit 10.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 9, 2008).
10.26	Guaranty Agreement dated as of January 3, 2008, executed by ImmuneRegen BioSciences, Inc. in favor of YA Global Investments, L.P. (incorporated by reference from Exhibit 10.2 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 9, 2008).
10.27	Security Agreement dated as of January 3, 2008, by and among the Company, YA Global Investments, L.P. and ImmuneRegen BioSciences, Inc. (incorporated by reference from Exhibit 10.3 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 9, 2008).
10.28	Patent Security Agreement dated as of January 3, 2008, by and among the Company, YA Global Investments, L.P. and ImmuneRegen BioSciences, Inc. (incorporated by reference from Exhibit 10.3 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on January 9, 2008).
10.29	Unsecured 12% Senior Promissory Note dated April 13, 2006 (incorporated by reference from Exhibit 10.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on April 19, 2006).
10.30	Unsecured 12% Senior Promissory Note dated July 25, 2006 in the amount of $250,000 (incorporated by reference from Exhibit 10.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 4, 2006).
10.31	Unsecured 12% Senior Promissory Note dated August 1, 2006 in the amount of $50,000 (incorporated by reference from Exhibit 10.2 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 4, 2006).

10.32	Unsecured 12% Senior Promissory Note dated August 1, 2006 in the amount of $20,000 (incorporated by reference from Exhibit 10.3 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 4, 2006).
10.33	Employment Agreement dated January 1, 2008 by and between the Company and John Fermanis (incorporated by reference from Exhibit 10.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on April 8, 2008).
10.34	Change of Control Agreement dated January 1, 2008 by and between the Company and John Fermanis (incorporated by reference from Exhibit 10.2 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on April 8, 2008).

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Exhibit Number	Description of Exhibit
10.35	Securities Purchase Agreement, dated as of August 8, 2008, by and among the Company, ImmuneRegen BioSciences, Inc., and certain funds managed by Brencourt Advisors, LLC (incorporated by reference from Exhibit 10.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 11, 2008).
10.36	Guaranty Agreement dated as of August 8, 2008, executed by ImmuneRegen BioSciences, Inc. in favor of certain funds managed by Brencourt Advisors, LLC (incorporated by reference from Exhibit 10.2 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 11, 2008).
10.37	Security Agreement dated as of August 8, 2008, by and among the Company, ImmuneRegen BioSciences, Inc., and certain funds managed by Brencourt Advisors, LLC (incorporated by reference from Exhibit 10.3 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 11, 2008).
10.38	Patent Security Agreement dated as of August 8, 2008, by and among the Company, ImmuneRegen BioSciences, Inc. and certain funds managed by Brencourt Advisors, LLC (incorporated by reference from Exhibit 10.4 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on August 11, 2008).
10.39	Employment Agreement dated October 24, 2008 by and between the Company and Hal Siegel (incorporated by reference from Exhibit 10.1 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 22, 2008).
10.40	Change of Control Agreement dated October 24, 2008 by and between the Company and Hal Siegel (incorporated by reference from Exhibit 10.2 to the Current Report on Form 8-K as filed with the Securities and Exchange Commission on December 22, 2008).
10.41	Employment Agreement dated February 2, 2010 by and between the Company and John N. Fermanis
10.42	Change of Control Agreement dated February 2, 2010 by and between the Company and John N. Fermanis
21.1	Subsidiaries of Registrant (incorporated by reference to exhibit 21.1 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).

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Exhibit Number	Description of Exhibit
31.1	Certification of Chief Executive Officer pursuant to Item 601(b)(31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Item 601(b)(31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
32.2	Certifications of Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*

* This exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any filings.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on May 24, 2011.

IR BIOSCIENCES HOLDINGS, INC.

Date: May 24, 2011	By:	/s/ Michael K. Wilhelm Michael K. Wilhelm President and Chief Executive Officer

In accordance with the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Michael K. Wilhelm	Chief Executive Officer, President and Director (Principal Executive Officer)	May 24, 2011
/s/ John N. Fermanis	Chief Financial Officer (Principal Financial and Accounting Officer)	May 24, 2011
/s/ Theodore E. Staahl, M.D.	Director	May 24, 2011
/s/ Hal N. Siegel, Ph.D.	Director	May 24, 2011
/s/ Lance K. Gordon, Ph.D.	Director	May 24, 2011

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SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

UNAUDITED FINANCIAL STATEMENTS AND SCHEDULES
DECEMBER 31, 2010 AND 2009

FORMING A PART OF ANNUAL REPORT
PURSUANT TO THE SECURITIES EXCHANGE ACT OF 1934

IR BIOSCIENCES HOLDINGS, INC.
(a development stage company)

IR BioSciences Holdings, Inc.
Index to Consolidated Financial Statements
(Unaudited)

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IR BioSciences Holdings, Inc. and Subsidiary
(A Development Stage Company)
Consolidated Balance Sheets
As of December 31, 2010 and December 31, 2009

	December 31, 2010 (Unaudited)	December 31, 2009
Assets		
Current assets		
Cash and cash equivalents	$-	$280,309
Prepaid services and other current assets (note 1)	44,930	68,347
Total current assets	44,930	348,656
Deposits and other assets (note 1)	-	7,693
Furniture and equipment, net of accumulated depreciation of $97,460 and $89,130, respectively (note 3)	20,866	29,197
Total assets	$65,796	$385,546
Liabilities and Stockholders' Deficit		
Current liabilities		
Cash overdraft	$24,147	$-
Accounts payable and accrued liabilities (note 4)	2,568,903	785,501
Current portion of notes payable (note 5)	3,613,895	2,000,000
Redemption option liability	300,000	300,000
Total current liabilities	6,506,945	3,085,501
Derivative liability (note 6)	895,153	2,256,200
Notes payable, net of discount of $3,006,498 in 2009 (note 5)	0	4,062,391
Total liabilities	7,402,098	9,404,092
Commitments and contingencies		
Preferred Stock	5,971,000	-
Stockholders' deficit (note 7)		
Preferred stock, $0.001 par value:		
10,000,000 shares authorized, no shares issued and outstanding	-	-
Common stock, $0.001 par value: 100,000,000 shares authorized;		
17,082,963 shares and 13,630,857 shares issued and outstanding		
at December 31, 2010 and December 31, 2009, respectively	17,082	13,630

Additional paid-in capital	19,713,733	18,717,575
Common stock subscribed (note 7)	-	10,222
Deficit accumulated during the development stage	(33,038,117)	(27,759,973)
Total stockholder's deficit	(13,307,302)	(9,018,546)
Total liabilities and stockholders' deficit	$65,796	$385,546

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

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IR BioSciences Holdings, Inc. and Subsidiary
(A Development Stage Company)
Consolidated Statements of Losses
For the years ended December 31, 2010 and 2009 and for
the period of Inception (October 30, 2002) to December 31, 2010

	For the Year Ended December 31, 2010 (Unaudited)	For the Year Ended December 31, 2009	Cumulative from Inception (October 30, 2002) to December 31, 2010 (Unaudited)
Revenue	$-	$-	$-
Operating expenses:			
Selling, general and administrative expenses	2,859,576	3,126,423	27,095,953
Merger fees and costs	-	-	350,000
Impairment of intangible asset	-	-	6,393
Total operating expenses	2,859,576	3,126,423	27,452,346
Operating loss	(2,859,576)	(3,126,423)	(27,452,346)
Other expense:			
Cost of penalty for late registration of shares	-	-	2,192,160
(Gain) loss from change in fair value of derivative liability	(4,738,450)	1,048,329	(8,401,072)
Loss on extinguishment of debt	5,431,861	-	5,431,861
Issuance of preferred shares for derivative expense	7,243	-	7,243
Financing cost	15,625	125,000	410,000
Interest expense, net	1,706,502	2,163,065	5,939,248
Total other expense	2,422,781	3,336,394	5,579,440
Loss before income taxes	(5,282,357)	(6,462,817)	(33,031,786)
Provision for income taxes	4,213	-	(6,331)
Net loss	$(5,278,144)	$(6,462,817)	$(33,038,117)
Preferred dividend	129,000	-	129,000
Net loss attributed to common stockholders	$(5,407,144)	$(6,462,817)	$(33,167,117)
Net loss per share - basic and diluted	$(0.34)	$(0.49)	$(3.77)
Weighted average shares outstanding - basic and diluted	15,790,184	13,182,213	8,797,972

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

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IR BioSciences Holding, Inc. and Subsidiary
(A Development Stage Company)
Consolidated Statement of Stockholders' Deficit
From date of inception (October 30, 2002) to December 31, 2010
(Unaudited)

	Common Stock		Paid-In	Additional Deferred	Stock	Common Accumulated	
	Shares	Amount	Capital	Compensation	Subscribed	Deficit	Total
Balance at October 30, 2002 (date of inception)	-	$ -	$ -	$ -	$ -	$ -	$ -
Shares of common stock issued at $0.006 per share to founders for license of proprietary right in December 2002	1,661,228	1,661	7,589	-	-	-	9,250
Shares of common stock issued at $0.006 per share to founders for services rendered in December 2002	140,531	141	641	-	-	-	782
Shares of common stock issued at $1.671 per share to consultants for services rendered in December 2002	5,388	5	8,995	(9,000)	-	-	-
		19	30,982	-	-	-	31,001

Sale of common stock for cash at $1.671 per share in December 2002	18,558						
Net loss for the period from inception (October 30, 2002) to December 31, 2002		-	-	-		(45,918)	(45,918)
Balance at December 31, 2002 (reflective of stock splits)	1,825,704	$ 1,826	$ 48,207	$ (9,000)	$ -	$ (45,918)	$ (4,885)

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IR BioSciences Holding, Inc. and Subsidiary
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Consolidated Statement of Stockholders' Deficit
From date of inception (October 30, 2002) to December 31, 2010

	Common Stock		Paid-In	Additional Deferred	Stock	Common Accumulated	
	Shares	Amount	Capital	Compensation	Subscribed	Deficit	Total
Shares granted to consultants at $1.392 per share for services rendered in January 2003	9,878	10	13,740	-	-	-	13,750
Sale of shares of common stock for cash at $1.517 per share in January 2003	32,955	33	49,967	-	-	-	50,000
Shares granted to consultants at $1.392 per share for services rendered in March 2003	15,445	15	21,485	-	-	-	21,500
Conversion of notes payable to common stock at $1.392 per share in April 2003	143,674	144	199,856	-	-	-	200,000
Shares granted to consultants at $1.413 per share for services rendered in April 2003	1,437	1	2,029	-	-	-	2,030
Sale of shares of common stock for cash at $2.784 per share in May 2003	1,796	2	4,998	-	-	-	5,000
Sales of shares of common stock for cash at $2.784 per share in June 2003	3,592	4	9,996	-	-	-	10,000

Conversion of notes payable to common stock at $1.392 per share in June 2003	71,837	72	99,928	-	-	-	100,000
Beneficial conversion feature associated with notes issued in June 2003		-	60,560	-	-	-	60,560
Amortization of deferred compensation	-	-	-	9,000	-	-	9,000
Costs of GPN Merger in July 2003	236,813	237	(121,036)	-	-	-	(120,799)
Value of warrants issued with extended notes payable in October 2003	-	-	189,937	-	-	-	189,937
							-
Value of Company warrants issued in conjunction with fourth quarter notes payable issued October through December 2003	-	-	207,457	-	-	-	207,457
Value of warrants contributed by founders in conjunction with fourth quarter notes payable issued October through December 2003	-	-	183,543	-	-	-	183,543
Value of warrants issued for services in October through	-	-	85,861	-	-	-	85,861

December 2003							
Net loss for the twelve month period ended December 31, 2003	-	-	-	-	(1,856,702)	(1,856,702)	-
Balance at December 31, 2003	2,343,130	$2,343	$1,056,529	$-	$-	$(1,902,620)	$(843,748)

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From date of inception (October 30, 2002) to December 31, 2010

	Common Stock		Paid-In	Additional Deferred	Stock	Common Accumulated	
	Shares	Amount	Capital	Compensation	Subscribed	Deficit	Total
Shares granted at $10.00 per share pursuant to the Senior Note Agreement in January 2004	60,000	60	599,940	(600,000)	-	-	-
Shares issued at $10.00 per share to a consultant for services rendered in January 2004	80,000	80	799,920	(800,000)	-	-	-
Shares issued to a consultant at $6.20 per share for services rendered in February 2004	4,000	4	24,796	(24,800)	-	-	-
Shares issued to a consultant at $4.00 per share for services rendered in March 2004	105,160	105	420,535	(420,640)	-	-	-
Shares issued to a consultant at $5.00 per share for services rendered in March 2004	50,000	50	249,950	(250,000)	-	-	-
Shares sold for cash at $1.50 per share in March, 2004	800	1	1,199	-	-	-	1,200
Shares issued at $5.00 per share	2,000	2	9,998	-	-	-	10,000

to consultants for services rendered in March 2004							
Shares issued to a consultant at $4.00 per share for services rendered in March 2004	200	0	800	-	-	-	800
Shares issued to consultants at $3.20 per share for services rendered in March 2004	9,160	9	29,303	-	-	-	29,312
Shares to be issued to consultant at $4.10 per share in April 2004 for services to be rendered through March 2005	-	-	-	(82,000)	-	-	(82,000)
Shares granted pursuant to the New Senior Note Agreement in April 2004	60,000	60	149,940	(150,000)	-	-	-
Shares issued to officer at $3.20 per share for services rendered in April 2004	20,000	20	63,980	-	-	-	64,000
Conversion of Note Payable to common stock at $1.00 per share in May 2004	35,000	35	34,965	-	-	-	35,000

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	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Deferred Compensation	Stock Subscribed	Accumulated Deficit	Total
Beneficial Conversion Feature associated with note payable in May 2004		-	35,000	-	-	-	35,000
Issuance of warrants to officers and founder for services rendered in May 2004	-	-	269,208	-	-	-	269,208
Shares to a consultant at $2.00 per share as a due diligence fee in May 2004	12,500	13	24,988	-	-	-	25,000
Shares issued to a consultant at $10.00 per share for services to be rendered over twelve months beginning May 2004	50,000	50	499,950	(500,000)	-	-	-
Beneficial Conversion Feature associated with notes payable issued in June 2004	-	-	3,000	-	-	-	3,000
Issuance of warrants to note holders in April, May, and June	-	-	17,915	-	-	-	17,915

2004							
Issuance of warrants to employees and consultants for services rendered in April through June 2004	-	-	8,318	-	-	-	8,318
Shares issued in July to a consultant at $1.00 for services to be rendered through July 2005	25,000	25	24,975	(25,000)	-	-	-
Shares issued to a consultant in July and September at $4.10 per share for services to be rendered through April 2005	20,000	20	81,980	-	-	-	82,000
Shares issued to a consultant in September at $1.20 to $2.20 for services rendered through September 2004	12,728	13	16,896	-	-	-	16,909
Shares issued in July to September 2004 as interest on note payable	30,000	30	35,970	-	-	-	36,000
Issuance of warrants with notes payable in July and August 2004	-	-	72,252	-	-	-	72,252

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	Common Stock		Paid-In	Additional Deferred	Stock	Common Accumulated	
	Shares	Amount	Capital	Compensation	Subscribed	Deficit	Total
Accrued deferred compensation in August 2004 to a consultant for 10,000 shares at $1.00 per share, committed but unissued	-	-	(10,000)	-	-	(10,000)	
Shares issued in August 2004 at $1.40 to a consultant for services to be performed through October 2004	10,000	10	13,990	(14,000)	-	-	-
Shares issued in August 2004 at $1.25 per share for conversion of $30,000 demand loan							