IR BIOSCIENCES HOLDINGS INC
Form 10KSB
March 31, 2008

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

FORM 10-KSB

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x	Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the fiscal year ended December 31, 2007
	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.)
8767 E. Via de Ventura, Suite 190, 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)

Check whether the issuer is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. o.

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act of 1934 during the past 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 x No o

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB. o

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

State issuer's revenues for its most recent fiscal year: $ 0.

The aggregate market value of the Registrant's issued and outstanding shares of common stock held by non-affiliates of the Registrant as of March 20, 2008 (based on the average of the bid and asked prices as reported by the FINRA OTC Bulletin Board as of that date) was approximately $5,728,761.

The number of shares outstanding of Registrant's Common Stock, par value $0.001 as of March 20, 2008: 115,622,539.

Documents Incorporated by reference: The information required by Part III of Form 10-KSB 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-KSB/A, not later than the end of the 120-day period.

Transitional Small Business Disclosure Format Yes o No x

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FORWARD-LOOKING STATEMENTS

THIS ANNUAL REPORT ON FORM 10-KSB CONTAINS FORWARD-LOOKING STATEMENTS THAT INVOLVE RISKS AND UNCERTAINTIES. IN PARTICULAR, STATEMENTS ABOUT OUR EXPECTATIONS, BELIEFS, PLANS, OBJECTIVES, ASSUMPTIONS OR FUTURE EVENTS OR PERFORMANCE ARE CONTAINED OR INCORPORATED BY REFERENCE IN THIS REPORT. WE HAVE BASED THESE FORWARD-LOOKING STATEMENTS ON OUR CURRENT EXPECTATIONS ABOUT FUTURE EVENTS. WHILE WE BELIEVE THESE EXPECTATIONS ARE REASONABLE, SUCH FORWARD-LOOKING STATEMENTS ARE INHERENTLY SUBJECT TO RISKS AND UNCERTAINTIES, MANY OF WHICH ARE BEYOND OUR CONTROL. THE ACTUAL FUTURE RESULTS FOR IR BIOSCIENCES HOLDINGS, INC. MAY DIFFER MATERIALLY FROM THOSE DISCUSSED HERE FOR VARIOUS REASONS, INCLUDING THOSE DISCUSSED IN THIS REPORT UNDER THE HEADING "RISK FACTORS," PART II, ITEM 6 ENTITLED "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS" AND ELSEWHERE THROUGHOUT THIS ANNUAL REPORT. GIVEN THESE RISKS AND UNCERTAINTIES, YOU ARE CAUTIONED NOT TO PLACE UNDUE RELIANCE ON SUCH FORWARD-LOOKING STATEMENTS. THE FORWARD-LOOKING STATEMENTS INCLUDED IN THIS REPORT ARE MADE ONLY AS OF THE DATE HEREOF. WE DO NOT UNDERTAKE AND SPECIFICALLY DECLINE ANY OBLIGATION TO UPDATE ANY SUCH STATEMENTS OR TO PUBLICLY ANNOUNCE THE RESULTS OF ANY REVISIONS TO ANY OF SUCH STATEMENTS TO REFLECT FUTURE EVENTS OR DEVELOPMENTS. WHEN USED IN THE REPORT, UNLESS OTHERWISE INDICATED, "WE," "OUR," "US," THE "COMPANY" OR "IMMUNEREGEN" REFERS TO IR BIOSCIENCES HOLDINGS, INC. AND ITS SUBSIDIARY, IMMUNEREGEN BIOSCIENCES, INC.

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PART I

ITEM 1. DESCRIPTION OF BUSINESS

OVERVIEW

IR BioSciences Holdings, Inc. is a development-stage biotechnology company. Through our wholly-owned subsidiary ImmuneRegen BioSciences, Inc., we are engaged in the research and development of potential drug candidates, Homspera™ and its derivatives, Radilex® and Viprovex®. Although containing the identical active ingredient Homspera, we defined Radilex and Viprovex as derivatives of Homspera due to the potential difference in formulations and indications for use. Our goals include developing these potential drug candidates to be used as possible countermeasures for homeland security threats, including radiological, chemical and biological agents, and to meet the commercial need for similar beneficial effects in conditions such as radiation therapy, influenza, anthrax and potentially other microbial ailments. We have discovered activities of Homspera that may potentially open additional commercialization opportunities in areas such as human adult stem cell stimulation, vaccine adjuvants, which stimulate the immune system above that of a stand-alone vaccine, and wound healing.

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.

Our current focus is to develop Homspera 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 disease using Homspera derivatives Radilex and Viprovex, respectively, which are described below. Recent studies have evaluated the effects of Homspera on human adult stem cell activity. Additionally, ongoing studies are being performed to evaluate the efficacy of Homspera as a potential product to increase the healing rate of wounds.

We are researching Radilex for use as a potential treatment for acute exposure to radiation. We believe that Radilex, if developed, may be an acceptable candidate to be marketed to governmental agencies for procurement. Further, we believe that a commercial market may exist for the 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 therapies.

Viprovex is being researched by us for use in potential treatments of exposure to biological agents, such as infectious disease, which include influenza and anthrax. We believe that Viprovex, if developed, can be used in potential applications for sale to governments for the treatment of exposure to anthrax and pandemic influenza. In addition, 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. 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. 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, such as formalin.

To date we have 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 and the other for the potential use of Viprovex in the treatment of avian influenza. We have contracted with an FDA regulatory consultant to assist us in our preparation and submission of an Investigational New Drug application (IND), a necessary prerequisite to human clinical studies, which can only follow after the FDA's allowance of our IND.

We have filed patent applications directed to various methods of using and compositions comprising Substance P analogues. We presently own at least five issued patents, including at least two issued U.S. patents and at least three issued foreign patents, one of which has been registered in nine countries in the European Union. We also have at least 61 pending patent applications, including at least 10 pending U.S. utility patent applications, at least 10 pending U.S. provisional applications, at least 4 pending international patent applications, and at least 37 pending foreign patent applications. All inventions embodied in these applications and issued patents have been assigned to the company by the inventors.

Our potential drug candidates, Homspera, Radilex and Viprovex, are at pre-clinical stages of development and may not be shown to be safe or effective and may never receive regulatory approval. Neither Homspera, Radilex nor Viprovex have been tested in large animals or humans. There is no guarantee that regulatory authorities will ever permit human testing of Homspera, Radilex, Viprovex or any other potential products derived from Homspera. Even if such testing is permitted, none of 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.

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.

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SUBSTANCE P AND HOMSPERA™

Our patents, patent applications and continued research relate to Substance P. 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 the replacement of 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.

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. It 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 also more persistent in the body.

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Applications

Through our wholly-owned subsidiary ImmuneRegen BioSciences, Inc., we are engaged in the research and development of potential drug candidates, Homspera and its derivatives, Radilex and Viprovex. Our goals include developing these potential drug candidates to be used as possible countermeasures for homeland security threats, including radiological, chemical and biological agents, and to meet the commercial need for similar beneficial effects in conditions such as radiation therapy, influenza, anthrax and potentially other microbial ailments. We have discovered activities of Homspera that may potentially open additional commercialization opportunities in areas such as vaccine adjuvants, which stimulate the immune system above that of a stand-alone vaccine, and human adult stem cell stimulation.

We use the trade names Radilex and Viprovex to differentiate the derivatives of Homspera. The active ingredient, Homspera, is chemically equivalent in both Radilex and Viprovex; however, since both Radilex and Viprovex are to be used in differing potential applications, and have distinct indications for use, we anticipate several formulations in the future that will support appropriate (and possibly different) modes of administration. For this reason, we have created the trade names to more easily differentiate the potential formulations, and applications, with respect to their development and potential future market opportunities.

The initial pre-clinical applications we are researching include: (i) stem cell activity/immune system strengthening (Homspera); (ii) wound healing (Homspera); (iii) treating the effects on the body caused by exposure to radiation (Radilex); (iv) treating the effects on the body caused by infectious disease and harmful biological materials (Viprovex); (v) vaccine adjuvants (Viprovex); and, (vi) treating the effects on the body caused by exposure to harmful chemical agents (Viprovex). In addition to these six potential applications, 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.

All our product candidates are in the pre-clinical stage of development. They have only been introduced to FDA via the pre-IND filings, submissions to which the FDA offers no judgment thereon. To date we have been issued two Pre-Investigational New Drug (PIND) numbers by the U.S. Food & Drug Administration (FDA). One is for the potential use of Radilex in the treatment of acute radiation syndrome and one is for the potential use of Viprovex in the treatment of avian influenza. The table below illustrates our current product candidates and their current stage of development within the FDA approval process.

Product Candidate	Pre-Clinical Mechanistic Studies	Animal Safety Studies	Phase I	Phase II	Phase III
Immune/Stem Cell Stimulant					
Homspera	In-progress	Planned			
Wound Healing					
Homspera	In-progress	Planned			
Acute Radiation Syndrome					
Radilex	In-progress	In-progress			
Infectious disease					
Viprovex	In-progress	In-progress			

Vaccine Adjuvant		
Viprovex	In-progress	In-progress
Chemical exposure		
Viprovex	In-progress	Planned

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The preliminary results of our pre-clinical studies using Homspera, Radilex or Viprovex 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, as well as had a positive effect on the immune system. 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.

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 exposures, dividing cells can suffer damage to their DNA and propagate that damage to their daughter cells, rendering them useless. Resting cells are less prone to the mutations observed in dividing cells as they have more time to repair their DNA using built-in molecular repair systems.

We have planned to conduct 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 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 hematopoietic stem cells to differentiate into blood-cell precursors. Study findings showed that Homspera stimulated adult hematopoietic stem cells to differentiate into early-stage white blood cells. 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, 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 survival of animals infected

with influenza. Additionally, there were decreased levels of virus in both the lungs and nasal passage in animals treated with Homspera. We also see 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 disease 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 the 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 accelerating wound healing, thus suggesting that Homspera may be a wound healing therapeutic.

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Preliminary cell culture studies have been performed to evaluate the effects of Homspera on the proliferation of some of the cells of the wound healing process. Homspera was found to increase the proliferation of cells in some of these studies, leading management to plan animal studies to evaluate the effect of Homspera in a more integrated, model of the wound healing process.

Such studies are currently being planned to evaluate the effects of Homspera on wound healing in established porcine (pig) models. Our co-development relationships with BioCure, Inc., DelSite Biotechnologies, Inc., and ULURU Inc. are structured to progress to the development of a potential controlled-release, Homspera wound healing product. Stand-alone studies are also being planned to evaluate the effects of Homspera alone using these same models.

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. We believe the results of these and other 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 Radilex, once and if developed, could be an acceptable candidate to be purchased by governmental agencies for national distribution in the event of a significant nuclear or radiological threat. Further, we hope 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.

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.

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 destroys 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 blood levels of white blood cells 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. In 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 Radilex, if developed, may be an acceptable candidate to be marketed to governmental agencies for procurement. Further, we believe that a commercial market may exist for the 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 therapies.

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 disease, 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. Performed in rodents, this study 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.

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, is a solution of formaldehyde gas dissolved in water and used industrially. 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 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. In addition, 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.

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 experience 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. These cells 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 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.

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 titers 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 lungs and, more noticeably, in nose. Further, in conjunction with the suggested anti-viral effect, animal weights and temperatures were normalized. Differences in cytokines, small peptide-signaling 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 vaccine adjuvant treating or mitigating the pathology associated with influenza infection.

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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Vaccine Adjuvant

Vaccine adjuvants are chemicals, traditionally co-administered with vaccines, which are designed to not stimulate an immune response when administered on their own but, rather improve the immune response to other, co-administered vaccines. Currently, the only FDA-approved adjuvants are alum, an aluminum salt and MPL, a bacterial membrane-derived lipid-carbohydrate. Adjuvants in development generally consist of derivatives of nucleic acids or lipids that most typically would be found within invading micro-organisms. 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.

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 and challenged by exposure to highly pathogenic virus at concentrations that ordinarily would be lethal to the mice.Viprovex-adjuvanted vaccine resulted an approximate 300% increase of influenza virus antibody levels in animals evaluated for Spanish-flu proteins and roughly 50% increase in animals evaluated for Avian flu proteins. This adjuvant activity correlated with enhanced survival after intranasal challenge with highly pathogenic avian (H5N1) influenza. Results indicated that only 33% of the Spanish flu-vaccinated animals survived challenge, while 100% of Spanish flu-vaccinated mice that received Viprovex survived.

Additional studies conducted with Viprovex in cell culture have shown an increased immune response to vaccine components as 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.

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. These tests will commence once results are analyzed from on-going formulation and mode of administration studies for Viprovex.

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.

Other Infectious Diseases

Melioidosis, also called Whitmore's disease, is an infectious disease caused by the bacterium Burkholderia pseudomallei, and is endemic to Southeast Asia and is seen in the South Pacific, Africa, India, and the Middle East as well. The causative agent, Burkholderia pseudomallei can be transmitted from animals to man as well as from person to person. The bacteria can be found in contaminated water and soil and is spread to humans and animals through direct contact with the contaminated source. Mortality rate for melioidosis varies and is as high as 90% particularly when aerosolized. The Centers for Disease Control and Prevention (CDC) considers both B. pseudomallei and its related B. mallei as potential agents for biological warfare and biological terrorism.

In the third quarter of 2007, we completed a study to investigate the therapeutic effects of Viprovex on acute melioidosis. This study was funded and performed in conjunction with Singapore's Defense Medical & Environmental Research Institute, DSO National Laboratories ("DSO"). Initial findings were unremarkable but further studies are planned.

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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 effect of jet fuel inhalation to inhibit the immune system, while administration of Substance P receptor (NK1) antagonists compounded the deleterious effects. Further experiments performed using Viprovex examined effectiveness in preventing lung injury on 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.

Formalin

Formalin is a solution of formaldehyde gas dissolved in water, used industrially and toxic typically via crosslinking of proteins to other nearby proteins. Formaldehyde is one of the 25 most abundantly produced chemicals in the world and has use in many industries. When dissolved in water at 30% to 50% formaldehyde, and often with methanol as a stabilizer, the resulting formalin solution is toxic to embryos and adult organisms.

We have conducted one pilot study to determine if aerosolized Viprovex could be effective in attenuating lung injury after formalin exposure. In this study of rats exposed to an aerosol application of formalin data suggests, in our opinion, that treatment with inhaled Viprovex may minimize lung damage concurrent with formalin inhalation.

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

DEVELOPMENT PROGRAM

Research and Development Spending

Due to our liquidity and limited cash available our spending on research and development activities has been limited. We spent approximately $455,017 and $484,029 in 2007 and 2006, respectively, in research and development activities related to the development of Homspera, Radilex and Viprovex. From our inception in October 2002, we have spent $1,481,614 in research and development activities. These costs only include the manufacture and delivery of our drug by third party manufacturers, payments to Contract Research Organizations and consultants for consulting related to our studies and costs of performing such studies. Significant costs relating to research and development, such as salary for Dr. Siegel, have been classified in officer salaries for consistency of financial reporting.

We anticipate that during the next 12 months we will increase our research and development spending to a total of approximately $800,000 in an effort to further develop Homspera, Radilex and Viprovex. This research and development cost estimate includes additional animal pharmacology studies, formulation and animal safety/toxicity studies. If we receive additional funds, through either investment funding or grants, we expect we will increase our research and development spending.

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.

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In August of 2007, Dr. Siegel, our Director and Senior Director of Product Development and Regulatory Affairs, made a presentation at the 2007 Biomedical Advanced Research and Development Authority (BARDA) Industry Day in Washington, D.C. The presentation highlighted our research and development activities pertaining to Homspera as a possible treatment for Acute Radiation Syndrome (ARS), Anthrax infection and pandemic influenza. The purpose of the forum is for companies interested in working with the Federal Government to showcase technological advances to agencies such as Project Bioshield, BARDA, and HHS.

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.

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 and T-Gen TD2.

Co-Development Relationships

Our co-development relationships generally involve some combination of sharing costs, combining technologies and know-how and/or profit-sharing with our co-development partners. Our current co-development partners are:

BioCure, Inc. We have entered into an agreement to develop wound healing treatment using Homspera with BioCure's proprietary spray-on hydrogel drug-delivery technology.

DelSite Biotechnologies, Inc. We have signed an agreement to develop wound healing treatment using Homspera with DelSite's proprietary polysaccharide drug delivering wound dressing. Additionally, the agreement entails the development of our vaccine adjuvant with DelSite's proprietary polysaccharide antigen delivery device.

ULURU Inc. We have entered into an agreement to develop a strategic partnership with ULURU Inc. to co-develop the combination of ULURU's hydrogel nanoparticle biomaterial and Homspera into a potential wound healing treatment.

Virion Systems, Inc. We have entered into a cost sharing and profit-sharing agreement to conduct animal studies on Viprovex as treatment for both seasonal and pandemic influenza.

GenPhar, Inc. We have entered into a cost sharing agreement to conduct animal studies on Viprovex as an adjuvant to GenPhar's proprietary cAdVax™ vaccine for influenza.

Advisory Boards and Consultants

To assist us in the research and development of our various applications we make use of outside consultants and advisory boards.

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Consultants

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

Dr. Joy A. Cavagnaro, Ph.D., DABT, RAC. Dr. Cavagnarois 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.

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.

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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.

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

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

MANUFACTURING

As previously discussed, we expect that 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.

As an analog of a naturally occurring substance, the compound itself is not proprietary; therefore, we have used and expect to continue to use third party manufacturers to obtain synthetic Homspera or Sar9, Met (O2)11-Substance P, the active ingredient in experimental formulations of Radilex and Viprovex. We believe Sar9, Met (O2)11-Substance P is readily available at low cost from several life science and technology companies that provide biochemical and organic chemical products used in scientific and genomic research, biotechnology, pharmaceutical development and the diagnosis of disease and chemical manufacturing. Further, we believe that the Sar9, Met (O2)11-Substance P is readily available from various sources, and several suppliers are capable of supplying such in both clinical and initial commercial quality and quantities.

Since to date we are only purchasing research quantities of the drug at this time, we have not entered into any contracts or agreements with any third party manufacturers, other than standard non-disclosure agreements.

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. We presently own at least five issued patents, including at least two issued U.S. patents and at least three issued foreign patents, one of which has been registered in nine countries in the European Union. We also have at least 61 pending patent applications, including at least 10 pending U.S. utility patent applications, at least 10 pending U.S. provisional applications, at least 4 pending international patent applications, and at least 37 pending foreign patent applications. All inventions embodied in these applications and issued patents have been assigned to the company by the inventors.

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 recently 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.

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.

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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.

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 January 8, 2008, we filed a declaration of actual use with the U.S.Patent and Trademark Office for Homspera with respect to biotechnology pharmaceuticals, namely adjuvants, counter-actants and immunostimulant products for enhancing the natural and reactive immunity to toxic agents. As of the date of this report, the application is still pending.

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.

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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.

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.

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.

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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.

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.

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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.

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.

SECURITIES LAWS

Because our common stock is registered under the Securities Exchange Act of 1934, as amended, and publicly traded, we are subject to a variety of rules and regulations of federal, state and financial market exchange entities charged with the protection of investors and the oversight of companies whose securities are publicly traded. These entities, including the Securities and Exchange Commission, the Public Company Accounting Oversight Board and the FINRA OTC Bulletin Board, have recently issued new requirements and regulations and are currently developing additional regulations and requirements in response to laws enacted by Congress, most notably the Sarbanes-Oxley Act of 2002. We do not know the exact level of resources we will have to commit in order to be in compliance. Our compliance with current and proposed rules is likely to require the commitment of significant financial and managerial resources. As a result, our management's attention might be diverted from other business concerns, which could negatively affect our business.

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DISTRIBUTION

If Radilex or Viprovex receives approval from the FDA, we will attempt to commercialize these applications. Upon such approval, if Radilex we intend to use our best efforts to market it as a treatment to the damaging effects of radiation injury that result after exposure to total body irradiation. If Viprovex, we intend to use our best efforts to market it as a medical countermeasure to the effects of exposure to various biological agents.

COMPETITIVE ENVIRONMENT

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.

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.

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.

EMPLOYEES

From our inception through the period ended December 31, 2007, we have relied primarily on the services of outside consultants for services. As of December 31, 2007, we had nine total employees: five full-time employees, two part-time employees and two contract employees. Our full-time employees are Michael K. Wilhelm, our Chief Executive Officer; John N. Fermanis, our Chief Financial Officer; Hal N. Siegel, Ph.D., Senior Director, Product

Development and Regulatory Affairs, a scientific program manager; and, the fifth serves in an administrative role. In order for us to attract and retain quality personnel, we anticipate we will have to offer competitive salaries to future employees. We do not anticipate our employment base will significantly change during the next twelve months, except that we plan on converting the two contract employees to full-time positions within our science department.

If we are able to expand our operations, we will incur additional costs for personnel. This projected increase in personnel is dependent upon our generating revenues and obtaining sources of financing. There is no guarantee that we will be successful in raising the funds required or generating revenues sufficient to fund the projected increase in the number of employees.

Our future success depends in large part upon our ability to attract and retain highly skilled scientific personnel. The competition in the scientific industry for such personnel is intense, and we cannot be sure that we will be successful in attracting and retaining such personnel. All of our employees are subject to employment agreements. We cannot guarantee that we will be able to replace any of our scientific personnel in the event their services become unavailable.

None of our employees are covered by collective bargaining agreements, and we believe our relations with our employees are favorable.

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RISK FACTORS

IN EVALUATING OUR BUSINESS, YOU SHOULD CONSIDER THE FOLLOWING DISCUSSIONS OF RISKS, IN ADDITION TO OTHER INFORMATION CONTAINED IN THIS REPORT AS WELL AS OUR OTHER PUBLIC FILINGS WITH THE SECURITIES AND EXCHANGE COMMISSION. ANY OF THE FOLLOWING RISKS COULD MATERIALLY ADVERSELY AFFECT OUR BUSINESS, FINANCIAL CONDITION, RESULTS OF OPERATIONS AND PROSPECTS.

Risks Related To Our Financial Results

We have limited cash resources, an accumulated deficit, are not currently profitable and expect to incur significant expenses in the near future.

As of December 31, 2007, we had a working capital deficit of $624,773. This amount consists of cash of $221,120, prepaid services of $84,691 and a salary advance of $2,025 less accounts payable and accrued liabilities of $932,609. We have incurred a net loss of $18,749,138 for the period from our inception in October 2002 to December 31, 2007, and have always experienced negative cash flow. We expect to continue to experience negative cash flow and operating losses through at least 2010 and possibly thereafter. As a result, we will need to generate significant revenues to achieve profitability.

We may fail to ever become and remain profitable or we may be unable to fund our continuing losses, in which case our business may fail.

We are focused on product development and have not generated any revenue to date. We do not believe we will begin earning revenues from operations until the calendar year 2009 as we transition from a development stage company. We have incurred operating losses since our inception. Our net loss for the fiscal year ended December 31, 2007 and December 31, 2006 was $5,463,958 and $1,486,046 respectively. As of December 31, 2007, we had an accumulated deficit of $18,749,138.

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

Our independent certified public accountants have stated in their report included in this Form 10-KSB that we have incurred a net loss and negative cash flows from operations of $5,463,958 and $2,456,038, respectively, for the year ended December 31, 2007. Our expectations to continue to incur net losses and negative cash flow from operations and a lack of operational history, among other matters, that raise substantial doubt about our ability to continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. The effect of this going concern would materially and adversely affect our ability to raise capital, our relationship with potential suppliers and customers, and have other unforeseen effects.

We will be required to raise additional capital to fund our operations. If we cannot raise needed additional capital in the future, we will be required to cease operations.

Based on our current plans, we believe our existing financial resources, and interest earned thereon, will be sufficient to meet our operating expenses and capital requirements through August, 2008. Additionally, in July 2008, we expect to sell and issue the remaining $1,000,000 of secured convertible debentures pursuant to our January 3, 2008 Securities Purchase Agreement with Y.A. Global Investments, L.P. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. We estimate that we will require an additional $5.0 million over the next 24 months in order to finance our research and development efforts, fund operating expenses, pursue regulatory clearances and prosecute and defend our

intellectual property rights. We may seek such additional funding through public or private financing or through collaborative arrangements with strategic partners.

You should be aware that in the future:

- we may not obtain additional financial resources when necessary or on terms favorable to us, if at all; and
- any available additional financing may not be adequate.

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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 August, 2008. 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.

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 $5.0 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, 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.

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, 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.

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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Risks Related To Our Business

If our plan is not successful or management is not effective, the value of our common stock may decline.

Our operating subsidiary, ImmuneRegen BioSciences, Inc., was founded in October 2002. We are a development stage company with a limited operating history that makes it impossible to reliably predict future growth and operating results. Our business and prospects must be considered in light of the risks and uncertainties frequently encountered by companies in their early stages of development. In particular, we have not demonstrated that we can:

- ensure that any potential drug candidate would function as intended in large animal studies or human clinical applications;
- obtain the regulatory approvals necessary to commercialize products that we may develop in the future;
- manufacture, or arrange for third-parties to manufacture, future products in a manner that will enable us to be profitable;
- establish many of the business functions necessary to operate, including sales, marketing, administrative and financial functions, and establish appropriate financial controls;
- make, use, and sell future products without infringing upon third party intellectual property rights; or
- respond effectively to competitive pressures.

We cannot be sure that we will be successful in meeting these challenges and addressing these risks and uncertainties. If we are unable to do so, our business will not be successful.

If we do not obtain government regulatory approval for our products, we cannot sell our products and we will not generate revenues.

Our principal development efforts are currently centered on Homspera, and derivatives thereof, Radilex and Viprovex. All drug candidates require U.S. Food and Drug Administration and 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.

All our 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.

If we fail to successfully develop and commercialize products, we will have to cease operations.

Our failure to develop and commercialize products successfully will cause us to cease operations. 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.

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Our current potential drug candidates, Homspera, 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 Homspera, 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 Homspera, Radilex, Viprovex or any other potential products derived from Homspera. Even if large animal or human testing is permitted, none of Homspera, 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.

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.

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.

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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 Homspera, 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.

If we fail to obtain approval from foreign regulatory authorities, we will not be allowed to market or sell our potential products in other countries, which would adversely affect our levels of future revenues, if any.

Marketing any drug products outside of the United States will subject us to numerous and varying foreign regulatory requirements governing the design and conduct of human clinical trials and marketing approval. Additionally, our ability to export our potential drug candidates outside the United States on a commercial basis will be subject to the receipt from the FDA of export permission, which may not be available on a timely basis, if at all.

Approval procedures vary among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Foreign regulatory approval processes include all of the risks associated with obtaining FDA approval set forth above, and approval by the FDA does not ensure approval by the health authorities of any other country.

Clinical trials may fail to demonstrate the safety and efficacy of our potential drug candidates, the effect of which could prevent or significantly delay regulatory approval and therefore adversely affect the timing and level of future revenues, if any.

Prior to receiving approval to commercialize Homspera, Radilex, Viprovex or any other potential products, if any, derived from Homspera, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA and other regulatory authorities in the United States and abroad, that they are both safe and effective. We will need to demonstrate such potential products' efficacy and monitor their safety throughout the process. If any future clinical trials are unsuccessful, our business and reputation would be harmed and our stock price would be adversely affected.

All of our applications are prone to the risks of failure inherent in biologic development. The results of early-stage clinical trials of our applications do not necessarily predict the results of later-stage clinical trials. Applications in later-stage clinical trials may fail to show desired safety and efficacy traits despite having progressed through initial clinical testing. Even if we believe the data collected from clinical trials of our applications is promising, this data may not be sufficient to support approval by the FDA or any other U.S. or foreign regulatory approval. Pre-clinical and

clinical data can be interpreted in different ways. Accordingly, FDA officials could interpret such data in different ways than we do which could delay, limit or prevent regulatory approval. The FDA, other regulatory authorities, or we may suspend or terminate clinical trials at any time. Any failure or significant delay in completing clinical trials for our applications, or in receiving regulatory approval for the sale of any products resulting from our applications, may severely harm our business and reputation.

Delays in the conduct or completion of our pre-clinical or clinical studies or the analysis of the data from our pre-clinical or clinical studies may result in delays in our planned filings for regulatory approvals or adversely affect our ability to enter into collaborative arrangements.

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We may encounter problems with some or all of our completed or ongoing studies that may cause us or regulatory authorities to delay or suspend our ongoing studies or delay the analysis of data from our completed or ongoing studies. If the results of our ongoing and planned studies for our drug candidates are not available when we expect or if we encounter any delay in the analysis of the results of our studies for our drug candidates:

- we may not have the financial resources to continue research and development of any of our drug candidates; and,
- we may not be able to enter into collaborative arrangements relating to any drug candidate subject to delay in regulatory filing.

Any of the following reasons, among others, could delay or suspend the completion of our ongoing and future studies:

- delays in enrolling volunteers;
- interruptions in the manufacturing of our drug candidates or other delays in the delivery of materials required for the conduct of our studies;
- lower than anticipated retention rate of volunteers in a trial;
- unfavorable efficacy results;
- serious side effects experienced by study participants relating to the drug candidate;
- new communications from regulatory agencies about how to conduct these studies; or,
- failure to raise additional funds.

Our lack of commercial manufacturing, sales, distribution and marketing experience may prevent us from successfully commercializing products, which would adversely affect our level of future revenues, if any.

The manufacturing process of Homspera, Radilex, Viprovex or any other potential products, if any, derived from Homspera is expected to involve a number of steps and requires compliance with stringent quality control specifications imposed by us and by the FDA. We have no experience in the sales, marketing and distribution of pharmaceutical or biotechnology products and we have not manufactured any of the limited quantities of Homspera, Radilex and Viprovex used in our studies to date. We may not successfully arrange for contract manufacturing of Homspera, Radilex, Viprovex or any other potential products, if any, derived from Homspera in production quantities and this could prevent us from commercializing products or limit our profitability from any such proposed products.

We rely on third party manufacturers for the manufacture of Radilex, Viprovex and Homspera. Our inability to manufacture Radilex, Viprovex and Homspera, and our dependence on such manufacturers, may delay or impair our ability to generate revenues, or adversely affect our profitability.

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.

We rely on arrangements with contract manufacturing companies in order to meet requirements for Radilex, Viprovex and Homspera. By choosing to contract for manufacturing services, we may encounter costs, delays and/or other difficulties in producing, packaging and distributing our clinical trials and finished product, if any. Further, contract manufacturers must also operate in compliance with the cGMP requirements; failure to do so could result in, among other things, the disruption of our proposed product supplies. Our planned dependence upon third parties for the manufacture of our proposed products may adversely affect our potential profit margins, if any, and our ability to develop and deliver proposed products on a timely and competitive basis.

If the manufacturers of our products do not comply with current good manufacturing practices regulations, or cannot produce the amount of products we need to continue our development, we will fall behind on our business objectives.

The manufacture of our product candidates or any future products, whether done by outside contractors as planned or internally, must comply with current Good Manufacturing Practices, or cGMP, regulations enforced by the FDA and foreign equivalents. If a manufacturer of our drug candidates does not conform to the cGMP regulations and cannot be brought up to such a standard, we will be required to find alternative manufacturers that do conform. This may be a long and difficult process, and may delay our ability to receive FDA or foreign regulatory approval of our products.

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We also rely on our manufacturers to supply us with a sufficient quantity of our drug candidates to conduct clinical trials. If we have difficulty in the future obtaining our required quantity and quality of such supply, we could experience significant delays in our development programs and regulatory process.

Even if we are permitted to market our potential products, adverse determinations concerning product pricing, reimbursement and related matters could prevent us from successfully commercializing Radilex, Viprovex and Homspera which would adversely affect our level of future revenues, if any.

Our ability to earn any revenue on Homspera, Radilex, Viprovex or any other potential products, if any, derived from Homspera will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health coverage insurers, managed care organizations and other organizations. Failure to obtain appropriate reimbursement may prevent us from successfully commercializing Homspera, Radilex, Viprovex or any other potential products, if any, derived from Homspera. Third-party payers are increasingly challenging the prices of medical products and services. If purchasers or users of Homspera, Radilex, Viprovex or any such other potential products, if any, derived from Homspera are not able to obtain adequate reimbursement for the cost of using such products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved health care products and whether adequate third party coverage will be available.

The medical community may not accept and utilize Homspera, Radilex, Viprovex or any other potential product, if any, derived from Homspera, the effect of which would prevent us from successfully commercializing any proposed product and adversely affect our level of future revenue, if any.

Our ability to market and commercialize Homspera, Radilex, Viprovex or any other potential product, if any, derived from Homspera depends on the acceptance of potential drug candidates based on Homspera by the medical community. We will need to develop commercialization initiatives designed to increase awareness about us and Homspera among targeted audiences, including public health activists and community-based outreach groups in addition to the investment community. Currently, we have not developed any such initiatives. Without such acceptance of potential drug candidates based on Homspera, we may not be able to successfully commercialize any proposed products or generate revenue.

Product liability exposure may expose us to significant liability or costs which would adversely impart our future operating results and divert funds from the operation of our business.

We face an inherent business risk of exposure to product liability and other claims and lawsuits in the event that the development or use of our technology or prospective products is alleged to have resulted in adverse effects. We may not be able to avoid significant liability exposure. We may not have sufficient insurance coverage, and we may not be able to obtain sufficient coverage at a reasonable cost. 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 may fail to protect adequately our proprietary technology, which would allow competitors to take advantage of our research and development efforts, the effect of which could adversely affect any competitive advantage we may have.

We have filed patent applications directed to various methods of using and compositions comprising substance P analogues. We presently own at least five issued patents, including at least two issued U.S. patents and at least three issued foreign patents, one of which has been registered in nine countries in the European Union. We also have at

least 61 pending patent applications, including at least 10 pending U.S. utility patent applications, at least 10 pending U.S. provisional applications, at least 4 pending international patent applications, and at least 37 pending foreign patent applications. All inventions embodied in these applications and issued patents have been assigned to the company by the inventors.

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 of 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.

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.

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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.

Failure to comply with environmental laws or regulations could expose us to significant liability or costs which would adversely impact our operating results and divert funds from the operation of our business have a material adverse effect on our business.

We may be required to incur significant costs to comply with current or future environmental laws and regulations. Our research and development processes involve the controlled storage, use and disposal of hazardous materials, biological hazardous materials and radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and some waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, the risk of contamination or injury from these materials cannot be completely eliminated. In the event of an incident, IR BioSciences Holdings, Inc. or ImmuneRegen BioSciences, Inc. could be held liable for any damages that result, and any liability could exceed our resources. Current or future environmental laws or regulations may have a material adverse effect on our operations, business and assets.

We depend on the continued services of our executive officers and the loss of a key executive could severely impact our operations.

The execution of our present business plan depends on the continued services of Michael K. Wilhelm, our Chief Executive Officer and President, and Hal Siegel, Ph.D., our Senior Director, Product Development and Regulatory Affairs.

We currently maintain a key-man life insurance policy on Mr. Wilhelm and Dr. Siegel for $1,000,000 and $250,000, respectively, payable to the company. 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. Additionally, our employment agreement with Michael Wilhelm is an At-Will agreement, meaning that either the Company or Mr. Wilhelm may terminate employment at any time for any reason with or without cause.

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 OTC Bulletin Board (the "OTCBB") under the symbol "IRBO". 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 American Stock Exchange. 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.

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.

Certain of our stockholders holding approximately 34,864,823 shares of common stock and 17,708,125 common stock purchase warrants have the right to register securities for resale that they hold pursuant to registration rights agreements. We also currently have $2 million in convertible debentures outstanding. The debentures are convertible at any time at the option of the holder into shares of the common stock at a price equal to $0.20 per share. On or after December 31, 2009 or if we fail to achieve certain milestones based on preclinical studies and submission of a Investigational New Drug Application, as set forth in the convertible debenture, the conversion price of the convertible debentures becomes the lower of (i) $0.20 per share or (ii) 80% of the lowest daily volume weighted average price during the five trading days immediately preceding conversion. In addition, we expect to continue to incur product development and selling, general and administrative costs, and in order to satisfy our funding requirements, we will need to sell additional equity securities, which may be subject to similar registration rights. The sale or the proposed sale of substantial amounts of our common stock in the public markets may adversely affect the market price of our common stock. The registration and subsequent sales of such shares of common stock will likely have an adverse effect on the market price of our common stock.

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Additionally, some of our shareholders 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 shareholder (or shareholders 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.

We may not have the ability to repurchase our secured convertible notes.

On January 3, 2008, we issued $2 million in secured convertible debentures (the "Convertible Debentures") and we have the option to issue to the buyer an additional $1 million of Convertible Debentures within the six months from the issuance. Obligations under the Convertible Debentures are guaranteed by our wholly-owned subsidiary and secured by all of our subsidiary's assets and property, including patents. The Convertible Debentures mature on December 31, 2010 and accrue interest at the rate of 8% per annum.

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 repurchase the Convertible Dentures. Any failure to repurchase the notes 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.

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.

ITEM 2. DESCRIPTION OF PROPERTY

Our corporate headquarters are currently located at 8767 E. Via de Ventura, Suite 190, Scottsdale, Arizona 85258, where we have leased approximately 3,322 square feet of office space for the period November 1, 2007 through October 31, 2009. Our minimum monthly rent expense is $6,921 plus tax per month in the first year and will increase to $7,128 plus tax per month in the second year. We will also be 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. We believe that our facilities are adequate for our current needs and suitable additional or substitute space will be available in the future to replace our existing facilities, if necessary, or accommodate expansion of our operations.

ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

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 2007.

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PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Our common stock is approved for quotation on the FINRA OTC Bulletin Board under the symbol "IRBO". The following table sets forth the high and low bid prices for our common stock for the periods noted, as reported by the National Daily Quotation Service and the Over-The-Counter Bulletin Board. Quotations reflect inter-dealer prices, without retail mark-up, markdown or commission and may not represent actual transactions.

	2008	
	High	Low
1st Quarter (through March 20, 2008)	$ 0.10	$ 0.02

	2007	
	High	Low
1st Quarter	$ 0.17	$ 0.12
2nd Quarter	0.21	0.12
3rd Quarter	0.23	0.14
4th Quarter	0.16	0.07

	2006	
	High	Low
1st Quarter	$ 0.35	$ 0.20
2nd Quarter	0.51	0.27
3rd Quarter	0.30	0.14
4th Quarter	0.29	0.13

On March 20, 2008 the closing price of our common stock as reported by the OTC Bulletin Board was $0.055 per share. There were approximately 800 shareholders of record of our common stock as of March 20, 2008. We have not paid any dividends on our common stock since inception and do not intend to do so in the foreseeable future.

UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On February 15, 2008, the Board of Directors approved of the issuance of 1,000,000 restricted shares of our common stock to Joseph Stevens & Co., Inc. and its designees, all of whom are accredited investors, per the terms of a consulting agreement dated November 20, 2007, under the terms of which the consultant would provide referral services for a term of one year to identify and introduce potential Directors to the company. 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.

Also on February 15, 2008, the Board of Directors approved of the issuance of 300,000 restricted shares of common stock to a consultant, who is an accredited investor, per the terms of a consulting agreement dated November 13, 2007, under the terms of which the consultant would provide investor relations services and consulting services for new product development for a term of four months. 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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On January 3, 2008, we entered into a securities purchase agreement with YA Global Investments, L.P., pursuant to which YA Global Investments, L.P. agreed to purchase from us (i) up to $3 million of secured convertible debentures, which shall be convertible into shares of our common stock and (ii) warrants to acquire up to 7,500,000 additional shares of our common stock. The initial closing occurred on January 3, 2008, at which time we sold to YA Global Investments, L.P. $2 million of the convertible debentures and the warrants. 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.

In April 2007, we issued warrants to purchase 5,000,000 shares of common stock to a consultant, who is an accredited investor. The warrants consist of three year warrants to purchase up to 4,000,000 shares of common stock exercisable at strike prices ranging from $.16 to $.30 per share and 1,000,000 five year warrants to purchase common stock exercisable at $.50 per share. 750,000 of the $0.16 strike price warrants vested immediately and the remainder vest in equal monthly installments of 177,083 over the 24 month term of the contract. The warrants have a net issue exercise provision to allow for cashless exercise unless and until the shares underlying the warrants are registered by us. 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 January 31, 2007, we issued 400,000 shares of common stock at a price of $0.155 per share to a consultant, who is an accredited investor, for services performed through June 2007. 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 January 31, 2007, we issued 100,000 shares of common stock at a price of $0.15 per share to a consultant, who is an accredited investor, for services performed through March 2007. 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 January 3, 2007, we issued 5,482,600 shares of our common stock to Joseph Stevens & Co., Inc. and its designees, all of whom are accredited investors, as commission for acting as placement agent for our private offering completed during the fourth quarter of 2006. Per the terms of our agreement, as additional commission, the placement agent, or its designees, were entitled to receive one share of common stock for each dollar of gross proceeds raised in the offering. The shares issued to the placement agent were offered in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

DIVIDENDS AND DISTRIBUTIONS

We have not paid any cash dividends to date. We intend to retain our future earnings, if any, and we do not anticipate paying cash dividends on our common stock in the foreseeable future.

EQUITY COMPENSATION PLANS

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

ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

THE FOLLOWING DISCUSSION CONTAINS FORWARD-LOOKING STATEMENTS THAT INVOLVE RISKS AND UNCERTAINTIES. SEE "FORWARD-LOOKING STATEMENTS" ABOVE. THIS DISCUSSION AND

ANALYSIS SHOULD BE READ IN CONJUNCTION WITH THE FINANCIAL STATEMENTS AND NOTES INCLUDED ELSEWHERE IN THIS REPORT.

This annual report on Form 10-KSB contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Please note that the safe harbor for forward-looking statements under the Securities Act of 1933 and the Securities Exchange Act do not apply to our company. Our actual results could differ materially from those set forth as a result of general economic conditions and changes in the assumptions used in making such forward-looking statements. The following discussion and analysis of our financial condition and results of operations should be read together with the audited consolidated financial statements and accompanying notes and the other financial information appearing else where in this report. The analysis set forth below is provided pursuant to applicable Securities and Exchange Commission regulations and is not intended to serve as a basis for projections of future events.

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EXCEPT FOR HISTORICAL INFORMATION CONTAINED HEREIN, THE MATTERS DISCUSSED IN THIS ANNUAL REPORT ARE FORWARD-LOOKING STATEMENTS THAT ARE SUBJECT TO CERTAIN RISKS AND UNCERTAINTIES THAT COULD CAUSE ACTUAL RESULTS TO DIFFER MATERIALLY FROM THOSE SET FORTH IN SUCH FORWARD-LOOKING STATEMENTS. SUCH FORWARD-LOOKING STATEMENTS MAY BE IDENTIFIED BY THE USE OF CERTAIN FORWARD-LOOKING TERMINOLOGY, SUCH AS "MAY," "EXPECT," "ANTICIPATE," "INTEND," "ESTIMATE," "BELIEVE," OR COMPARABLE TERMINOLOGY THAT INVOLVES RISKS OR UNCERTAINTIES. ACTUAL FUTURE RESULTS AND TRENDS MAY DIFFER MATERIALLY FROM HISTORICAL AND ANTICIPATED RESULTS, WHICH MAY OCCUR AS A RESULT OF A VARIETY OF FACTORS. SUCH RISKS AND UNCERTAINTIES INCLUDE, WITHOUT LIMITATION, FACTORS DISCUSSED IN MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS SET FORTH BELOW, AS WELL AS IN "RISK FACTORS" SET FORTH HEREIN. EXCEPT FOR OUR ONGOING OBLIGATION TO DISCLOSE MATERIAL INFORMATION AS REQUIRED BY FEDERAL SECURITIES LAWS, WE DO NOT INTEND TO UPDATE YOU CONCERNING ANY FUTURE REVISIONS TO ANY FORWARD-LOOKING STATEMENTS TO REFLECT EVENTS OR CIRCUMSTANCES OCCURRING AFTER THE DATE OF THIS ANNUAL REPORT.

CORPORATE 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 shareholders voted to increase the number of authorized shares of Common Stock to 250,000,000. 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.

RECENT EVENTS

On January 3, 2008, we entered into a securities purchase agreement with YA Global Investments, L.P., pursuant to which YA Global Investments, L.P. agreed to purchase from us (i) up to $3 million of secured convertible debentures, which shall be convertible into shares of our common stock and (ii) warrants to acquire up to 7,500,000 additional shares of our common stock. The initial closing occurred on January 3, 2008, at which time we sold to YA Global Investments, L.P. $2 million of the convertible debentures and the warrants. The company, at our sole option, may elect to sell and issue to YA Global Investments, L.P. an additional $1 million of secured convertible debentures within the six months following the execution of the securities purchase agreement. See Note 10 to the notes to the financial statements for more information.

On November 1, 2007, the Board of Directors appointed a new director, Jerome Bernard Zeldis, M.D., Ph.D., to our Board of Directors to fill a vacant directorship. We and Dr. Zeldis entered into a Director's Agreement dated October 30, 2007 which describes the duties of Dr. Zeldis, the fees and compensation and expense reimbursement for his service, subject to the Board's approval, the grant of 1,000,000 non-qualified stock options to Dr. Zeldis for service as a director, his term of service and other covenants and provisions. As of December 31, 2007, the Board has not approved the non-qualified stock issuance.

On October 25, 2007, we entered into a two year lease agreement with Bay Colony Executive Center-West, a division of BC Management Company, Inc. pursuant to which we will lease approximately 3,322 square feet of office space for the period November 1, 2007 through October 31, 2009, to serve as our new corporate headquarters which are located at 8767 E. Via de Ventura, Suite 190, Scottsdale, Arizona 85258. Our minimum monthly rent expense is $6,921 plus tax per month in the first year and will increase to $7,128 plus tax per month in the second year. We will also be responsible for its 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.

On August 6, 2007 we repaid an unsecured senior promissory note from a director in the amount of $56,000, the outstanding principal amount of the note plus accrued interest in the amount of $6,000. Effective August 1, 2006, we had converted a cash advance from such director into an unsecured senior promissory note in the amount of $50,000 bearing an annual interest rate of 12%.

On August 1, 2007 the Board of Directors approved by Unanimous Written Consent to grant stock option awards totaling ten million stock options to officers, directors and consultants pursuant to the terms of the 2003 Stock Option, Deferred Stock and Restricted Stock Plan. The awards are as follows: 6,060,000 stock options were issued to Officers and employees in the form of incentive stock options with a strike price of $0.195 per share and non-qualified stock options with a strike price equal to $0.166 per share; 3,250,000 non-qualified stock options with a strike price equal to $0.166 per share were issued to directors per the terms of their agreements, or for reaching certain milestones: and lastly, 690,000 non-qualified stock options with strike prices ranging from $0.166 per share to $0.195 per share were issued to consultants per the terms of their agreements or as bonuses.

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On May 14, 2007, the Board of Directors appointed a new director, Lance K. Gordon, Ph.D., to our Board of Directors to fill a vacant directorship. For his service as a member of our Board of Directors, we granted to Dr. Gordon under the Company's 2003 Stock Option, Deferred Stock and Restricted Stock Plan, a non-qualified stock option to purchase 1,000,000 shares of common stock at an exercise price per share equal to $0.166 expiring on July 31, 2017 to vest within 30 days from the date of the grant.

On April 24, 2007, our Board of Directors appointed a new director, Robert J. Hariri, M.D., Ph.D., to our Board of Directors to fill a vacant directorship. For his service as a member of our Board of Directors, we granted to Dr. Hariri under the Company's 2003 Stock Option, Deferred Stock and Restricted Stock Plan, a non-qualified stock option to purchase 1,000,000 shares of common stock at an exercise price per share equal to $0.166 expiring on July 31, 2017 to vest within 30 days from the date of the grant.

On April 23, 2007, we entered into a consulting agreement for a term of 24 months to obtain strategic advisory and development services. Consultant will analyze our business plan and prepare corporate materials for dissemination to related industry professionals to be used for identifying potential acquisition candidates, partners and collaborators. We will pay to consultant a monthly cash fee of $4,000. In addition, consultant will be issued up to 5,000,000 common stock purchase warrants with a net issue exercise provision to allow for cashless exercise unless and until the shares underlying the warrants are registered by us. The warrants shall consist of three year warrants to purchase up to 4,000,000 shares of common stock exercisable at strike prices ranging from $.16 to $.30 per share and 1,000,000 five year warrants to purchase common stock exercisable at $.50 per share. 750,000 of the $0.16 strike price warrants will vest immediately and the remainder will vest in equal monthly installments over the 24 month term of the contract. The contract is cancellable by either party for any reason by providing 30 days written notice and the warrants contain forfeiture provisions as to all unvested warrants in the event the agreement is terminated prior to vesting date.

In April 2007, we issued warrants to purchase 5,000,000 shares of common stock to a consultant. The warrants vest 750,000 immediately and 177,083 every month for the next two years. We charged to operations the amount of $166,997 the value of the warrants that vested during the twelve months ended December 31, 2007.

In January 2007, we issued 5,482,600 restricted shares of our common stock to Joseph Stevens & Co., Inc. and its designees as commission for acting as placement agent for our private offering completed during the fourth quarter of 2006. Per the terms of our agreement, as additional commission, the placement agent, or its designees, were entitled to receive one share of common stock for each dollar of gross proceeds raised in the offering. These shares were shown as common stock subscribed on our balance sheet at December 31, 2006.

In January 2007, we issued 298,039 shares of common stock at a price of $0.15 per share to an employee in satisfaction of a liability previously accrued.

In January 2007, we issued 400,000 shares of common stock at a price of $0.155 per share to a consultant for services to be performed through June 2007.

In January 2007, we issued 100,000 shares of common stock at a price of $0.15 per share to a consultant for services to be performed through March 2007.

In January 2007, we issued options to purchase 100,000 shares of common stock an employee. The options vest 12,500 every quarter for the next two years.

GENERAL

IR BioSciences Holdings, Inc. is a development-stage biotechnology company. Through our wholly-owned subsidiary ImmuneRegen BioSciences, Inc., we are engaged in the research and development of potential drug candidates, Homspera™ and its derivatives, Radilex® and Viprovex®. Although containing the identical active ingredient Homspera, we defined Radilex and Viprovex as derivatives of Homspera due to the potential difference in formulations and indications for use. Our goals include developing these potential drug candidates to be used as possible countermeasures for homeland security threats, including radiological, chemical and biological agents, and to meet the commercial need for similar beneficial effects in conditions such as radiation therapy, influenza, anthrax and potentially other microbial ailments. We have discovered activities of Homspera that may potentially open additional commercialization opportunities in areas such as human adult stem cell stimulation, vaccine adjuvants, which stimulate the immune system above that of a stand-alone vaccine, and wound healing.

Our current focus is to develop Homspera 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 disease using Homspera derivatives Radilex and Viprovex, respectively, which are described below.

We are researching Radilex for use as a potential treatment for acute exposure to radiation. We believe that Radilex, if developed, may be an acceptable candidate to be marketed to governmental agencies for procurement. Further, we believe that a commercial market may exist for the 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 therapies.

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Viprovex is being researched by us for use in potential treatments of exposure to biological agents, such as infectious disease, which include influenza and anthrax. We believe that Viprovex, if developed, can be used in potential applications for sale to governments for the treatment of exposure to anthrax and pandemic influenza. In addition, we believe that potential commercial opportunities may exist for the treatment of seasonal influenza and other viral or bacterial infections, either as a stand-along drug or as an adjuvant to other existing drugs. 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, such as formalin.

Recent studies have evaluated the effects of Homspera on human adult stem cell activity. Additionally, ongoing studies are being performed to evaluate the efficacy of Homspera as a potential product to increase the healing rate of wounds.

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.

PLAN OF OPERATIONS

We expect to continue to incur increasing operating losses for the foreseeable future, primarily due to our continued research and development activities attributable to Homspera, Radilex, Viprovex or any other proposed product, if any, derived from Homspera and general and administrative activities.

The preliminary results of our pre-clinical studies using Homspera, Radilex or Viprovex 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."

PRODUCT RESEARCH AND DEVELOPMENT

Due to our liquidity and limited cash available our spending on research and development activities in the years ended December 31, 2006 and 2007 was limited. We spent approximately $541,589 and $484,029 in 2007 and 2006, respectively, in research and development activities related to the development of Homspera, Radilex and Viprovex. From our inception in October 2002, we have spent $1,568,186 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. Significant costs relating to research and development, such as compensation for Dr. Siegel have been classified in officer’s salaries for consistency of financial reporting.

We anticipate that during the next 12 months we will increase our research and development spending to a total of approximately $800,000 in an effort to further develop Homspera, Radilex and Viprovex. This research and development cost estimate includes additional animal pharmacology studies, formulation and animal safety/toxicity studies. If we receive additional funds, through investment funding, licensing agreements or grants, we expect we will further increase our research and development spending.

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 year 2009. 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, 2007, we had no revenues from any product sales, royalties or licensing fees, and 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.

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.

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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.

OFF-BALANCE SHEET ARRANGEMENTS

There were no off-balance sheet arrangements made in 2007.

REVENUES

We have not generated any revenues from operations from our inception. We believe we will begin earning revenues from operations during calendar year 2009 as we transition from a development stage company.

COSTS AND EXPENSES

From our inception through December 31, 2007, we have incurred losses of $18,749,138. These expenses were associated principally with equity-based compensation to employees and consultants, product development costs and professional services, and equity based compensation to shareholders for the penalty incurred for the late registration of shares.

For the twelve months ending December 31, 2007, Sales, General and Administrative expenses (“SG&A”) were $5,516,323, an increase of $3,071,006 or approximately 125% compared to SG&A expenses of $2,445,317 during the 12 months ended December 31, 2006. The year over year increase was primarily due to an increase of $2,468,218 for the costs of non-cash compensation and also to a one-time adjustment in 2006 that resulted in a net gain of $1,007,779 relating to the cost of penalty for late registration of shares, as more fully described below.

For the twelve months ending December 31, 2007, Interest Income (net) was $62,909 an increase of approximately 230% compared to Interest Expense (net) of $48,508 during the 12 months ended December 31, 2006. Interest Income increased because we repaid all outstanding notes payable during the twelve months ended December 31, 2007 and earned interest on the proceeds of a private placement that we conducted in December 2006. We expect Interest Expense to increase during the coming twelve months as we will accrue interest expenses on the convertible debenture we issued in January 2008.

NET LOSS

For the reasons stated above, our net loss for the twelve months ending December 31, 2007 was $5,463,958, or $0.05 per share versus a net loss for the twelve months ending December 31, 2006 of $1,486,046 or $0.02 per share. For the period of inception (October 30, 2002) through December 31, 2007, our net loss was $18,749,138, or $0.38 per share. We expect that losses will continue through the period ending December 31, 2010.

We have incurred a net loss and negative cash flows from operations of $5,463,958 and $2,456,038, respectively, for the year ended December 31, 2007. This loss, in addition to a lack of operational history, raises substantial doubt about our ability to continue as a going concern. Management believes we currently have sufficient working capital to fund operations through August, 2008. Additionally, in July of 2008, we expect to sell and issue the remaining $1,000,000 of secured convertible debentures pursuant to the January 3, 2008, Securities Purchase Agreement with Y.A. Global Investments, L.P. 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 future operations, 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 August, 2008. 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.

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Penalties for Late Registration

In October 2004, we completed a private placement sale of shares of our common stock and warrants to purchase additional shares of common stock. We issued in the private placement an aggregate of 19,600,000 shares of our common stock and warrants to purchase 9,800,000 shares of our common stock. We agreed to register these shares along with the shares underlying these warrants within ninety days from the closing date of the transaction, or we would incur a penalty equivalent to an additional 2% of the shares and warrants to be registered for every 30 days that we failed to complete this registration. This penalty amounts to an aggregate of 461,200 shares and 181,600 warrants per 30 day period until such a time as this registration statement is made effective. We were unable to register the securities as required.

We attempted to register the shares and warrants by filing a registration statement with the Securities and Exchange Commission on November 24, 2004, and amended this registration statement with pre-effective amendments no. 1, 2, 3 and 4 on July 20, 2005, November 16, 2005, February 22, 2006 and April 7, 2006, respectively. On July 10, 2006 we, pursuant to Rule 477 of Regulation C of the Securities Act of 1933, as amended, applied for an order granting the immediate withdrawal of the Registration Statement on Form SB-2.

In August 2006, we reached an agreement with the investors in the private placement of October 2004 which limits the number of warrants and shares which we are obligated to issue pursuant to the penalty calculation to an aggregate of 18% of the number of original number of shares and warrants issued in the October 2004 private placement. This agreement limits the number of shares and warrants issuable pursuant to the penalty calculation to an aggregate of 4,150,798 shares and warrants to purchase an additional 1,634,400 shares, respectively. This resulted in a decrease in the number of share issuable 2,475,107 (with a fair value of $816,785) and a decrease in the number of warrant shares of 974,587 (with a fair value of $177,789). This resulted in a net realized gain of $438,601 during the twelve months ended December 31, 2006.

In August 2006, we issued 4,150,798 shares and warrants to purchase 1,634,400 shares and relieved accrued liabilities in the aggregate amount of $1,053,904. For the twelve months ended December 31, 2006, we marked to market the value of the shares and warrants issuable pursuant to the penalty calculation for an aggregate gain in the amount of approximately $445,673 and $123,505, respectively.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2007, we had current assets of $307,836 consisting of cash of $221,120 and prepaid services of $84,691. Also, at December 31, 2007, we had current liabilities of $932,609, consisting of accounts payable and accrued liabilities of $932,609 and notes payable of $0. This resulted in a working capital deficit of $624,773. During the twelve months ended December 31, 2007, we used cash in operating activities of $2,456,038. From the date of inception (October 30, 2002) to December 31, 2007, we had a net loss of $18,749,138 and used cash of $8,449,980 in operating activities. We met our cash requirements from our inception through December 31, 2007 via the private placement of $7,877,901 of our common stock and $858,628 from the issuance of notes payable, net of repayments.

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.

On January 3, 2008, we entered into a securities purchase agreement with YA Global Investments, L.P., pursuant to which YA Global Investments, L.P. agreed to purchase from us (i) up to $3 million of secured convertible debentures, which shall be convertible into shares of our common stock and (ii) warrants to acquire up to 7,500,000 additional shares of our common stock. The initial closing occurred on January 3, 2008, at which time we sold to YA Global Investments, L.P. $2 million of the convertible debentures and the warrants. The company, at our sole option, may elect to sell and issue to YA Global Investments, L.P. an additional $1 million of secured convertible debentures within the six months following the execution of the securities purchase agreement.

In December 2006, we completed a private placement, whereby we sold an aggregate of $5,482,600 worth of units 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, we would file with the SEC an appropriate registration statement to register these shares along with the shares underlying these warrants. In the event that we had failed to comply with the filing deadline, there would have been a 1% penalty for each 30 day period (or pro rata portion thereof) paid to each investor in cash or additional shares. This penalty would have amounted to an aggregate of 342,662 shares and 171,331 warrants per 30 day period until such time as a registration statement that included these shares and warrants was filed or for 12 months. As of December 31, 2007, we are not subject to any penalty.

Pursuant to our employment agreement with Michael Wilhelm, our President and Chief Executive Officer, dated December 16, 2002, we paid a salary of $125,000 and $175,000 to Mr. Wilhelm during the first and second years of his employment, respectively. Thereafter we paid through August 10, 2005, an annual salary of $250,000. On August 10, 2005, we entered into a new employment agreement with Mr. Wilhelm. The new employment agreement is an At-Will agreement, meaning that the Company or Mr. Wilhelm may terminate employment at any time for any reason with or without cause, and calls for a salary at the rate of $275,000 per annum and provides for annual salary increases of 10% and bonus incentives. Mr. Wilhelm's salary is payable in regular installments in accordance with the customary payroll practices of our Company.

Pursuant to our employment agreement with John Fermanis, our Chief Financial Officer, dated February 15, 2005, we paid a salary of $60,000 until the company completed a financing of $500,000 or more. This occurred on March 4, 2005 when the company completed a tender offer for warrants totaling $1,211,000 net of fees. From March 4, 2005, until December 31, 2005, we paid an annual salary of $85,000. Thereafter, we paid an annual salary of $98,000 for the second year ending December 31, 2006 and paid an annual salary of $112,000 for the third year ending December 31, 2007. Mr. Fermanis' salary is payable in regular installments in accordance with the customary payroll practices of our Company.

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Pursuant to our employment agreement with Hal N. Siegel, our Senior Director of Product Development and Regulatory Affairs, dated October 23, 2006, we will pay an annual base salary of $200,000 for the first year and $210,000 for the second year. Mr. Siegel will also be eligible for discretionary bonuses under the Company's stock option plan during his employment. In addition, Mr. Siegel received options with a term of five years to purchase 200,000 shares of common stock of the Company. The options are exercisable at $0.20 per share. The employment agreement has a term of two years, subject to early termination provisions. Upon termination of Mr. Sigel's employment by the Company without cause or constructive termination, as defined in the agreement, the Company agrees to pay to Mr. Siegel the remainder of his salary for the year or six months salary, whichever is greater, and any accrued vacation.

Pursuant to the terms of the change of control agreement, the Company agrees to pay Mr. Siegel his salary for a period of 18 months from the date an involuntary termination, payable in accordance with the Company's compensation practice. Involuntary termination is defined as the termination of Mr. Siegel's employment by Company without cause or due to constructive termination at any time within one-year from a change of control event, as defined in the agreement.

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 2004 to December 31, 2007, we were able to obtain financing of $9,097,736 from a series of private placements of our securities (which resulted in net proceeds to us of $7,877,901). In January 2008 we sold $2 million in secured convertible debentures which resulted in net proceeds to us of $1,815,000. We also expect to sell an additional $1 million of the secured convertible debentures after July 3, 2008 as per the terms of the securities purchase agreement with YA Global Investments L.P. Based on our current plan of operations all of our current funding is expected to be depleted by the end of August, 2008. The additional $1 million is expected to fund operations until January 2009. 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.

Our independent registered certified public accountants have stated in their report included in this Form 10-KSB that the Company's recurring losses and negative cash flow raise substantial doubt about the Company's ability to continue as a going concern.

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 or seeking an acquisition partner.

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. Based on our operating expenses and anticipated research and development activities we believe we have sufficient to

meet or operating needs through August, 2008. Thereafter, we believe that we will require an additional $2,500,000 to meet our expenses over the next 12 months.

Acquisition or Disposition of Plant and Equipment

We acquired $24,945 worth of property, plant or equipment for the year ended December 31, 2007. We do not anticipate the acquisition or disposition of any significant property, plant or equipment during the next 12 months.

Number of Employees

From our inception through the period ended December 31, 2007, we have relied primarily on the services of outside consultants for services. As of December 31, 2007 we had nine total employees: five full-time employees, two part-time employees and two contract employees. Our full-time employees are Michael K. Wilhelm, our Chief Executive Officer; John N. Fermanis, our Chief Financial Officer; Hal N. Siegel, Ph.D., Senior Director, Product Development and Regulatory Affairs, a scientific program manager; and, the fifth serves in an administrative role. In order for us to attract and retain quality personnel, we anticipate we will have to offer competitive salaries to future employees. We do not anticipate our employment base will significantly change during the next twelve months, except that we plan on converting the two contract employees to full-time positions within our science department.

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CRITICAL ACCOUNTING POLICY

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:

Stock-based Compensation

Effective January 1, 2006, the Company adopted SFAS No. 123 (revised), "Share-Based Payment" (SFAS 123(R)) utilizing the modified prospective approach. Prior to the adoption of SFAS 123(R) we accounted for stock option grant in accordance with APB Opinion No. 25, "Accounting for Stock Issued to Employees" (the intrinsic value method), and accordingly, recognized compensation expense for stock option grants.

Under the modified prospective approach, SFAS 123(R) applies to new awards and to awards that were outstanding on January 1, 2006 that are subsequently modified, repurchased or cancelled. Under the modified prospective approach, compensation cost recognized in the nine months of fiscal 2006 includes compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS 123, and compensation cost for all share-based payments granted subsequent to January 1, 2006 based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R). Prior periods were not restated to reflect the impact of adopting the new standard.

A summary of option activity under the Plan as of December 31, 2007, and changes during the period ended are presented below:

	Options	Weighted Average Exercise Price
Outstanding at December 31, 2006	5,914,212	$ 0.50
Issued	10,100,000	0.17
Exercised	-	-
Forfeited or expired	-	-
Outstanding at December 31, 2007	16,014,212	$ 0.29
Non-vested at December 31, 2007	100,000	$ 0.16
Exercisable at December 31, 2007	15,914,212	$ 0.29

Aggregate intrinsic value of options outstanding and exercisable at December 31, 2007 was $0. Aggregate intrinsic value represents the difference between the Company's closing stock price on the last trading day of the fiscal period, which was $0.08 as of December 31, 2007, and the exercise price multiplied by the number of options outstanding. As of December 31, 2007, total unrecognized stock-based compensation expense related to stock options was $24,840 . During the year ended December 31, 2007, the Company charged $482,771 to operations related to recognized stock-based compensation expense for employee stock options.

Recent Accounting Pronouncements

In February 2007, the FASB issued SFAS No. 159, “The Fair Value Option for Financial Assets and Financial Liabilities.” SFAS 159 permits entities to choose to measure many financial instruments, and certain other items, at fair value. SFAS 159 applies to reporting periods beginning after November 15, 2007. The adoption of SFAS 159 is not expected to have a material impact on the Company’s financial condition or results of operations.

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ITEM 7. FINANCIAL STATEMENTS

IR BIOSCIENCES HOLDINGS, INC.

IR BioSciences Holdings, Inc. and Subsidiary
(A Development Stage Company)
Index to Consolidated Financial Statements

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REPORT OF INDEPENDENT REGISTERED CERTIFIED PUBLIC ACCOUNTING FIRM

The Board of Directors
IR BioSciences Holdings, Inc.
Scottsdale, Arizona

We have audited the accompanying consolidated balance sheets of IR Biosciences Holdings, Inc. and Subsidiary ("Company"), a development stage company, as of December 31, 2007 and 2006, and the related consolidated statements of losses, deficiency in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2007 and for the period October 30, 2002 (date of inception as a development stage enterprise) to December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States of America). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of IR BioSciences Holdings, Inc. as of December 31, 2007, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2007 and from October 30, 2002 (date of inception as a development stage enterprise) to December 31, 2007 in conformity with generally accepted accounting principles in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note A to the financial statements, the Company has suffered recurring losses from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note A. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ RBSM LLP
Certified Public Accountants

New York, New York
March 28, 2008

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IR BioSciences Holdings, Inc. and Subsidiary
(A Development Stage Company)
Consolidated Balance Sheets as of December 31, 2007
And December 31, 2006

	December 31, 2007	December 31, 2006
Assets		
Current assets		
Cash and cash equivalents	$ 221,120	$ 2,752,103
Prepaid services and other current assets (Note 1)	84,691	77,899
Salary advance (Note 1)	2,025	1,500
Total current assets	307,836	2,831,502
Deposit (Note 1)	7,128	2,260
Furniture and equipment, net of accumulated depreciation of $27,158 and $12,242 (Note 2)	38,271	28,242
Total assets	$ 353,235	$ 2,862,004
Liabilities and Stockholders' (Deficit) Equity		
Current liabilities		
Accounts payable and accrued liabilities (Note 3)	932,609	460,969
Current portion of Notes Payable	-	50,000
Total current liabilities	932,609	510,969
Commitments and Contingencies (Note 8)	-	-
Stockholders' (Deficit) Equity		
Preferred stock, $0.001 par value: 10,000,000 shares authorized, no shares issued and outstanding	-	-
Common stock, $0.001 par value; 250,000,000 shares authorized; 114,322,539 and 108,041,897 shares issued and outstanding at December 31, 2007 and December 31, 2006, respectively (Note 6)	114,323	108,042
Additional paid-in capital	17,902,441	15,522,690
Common stock subscribed (Note 6)	153,000	5,483
Deficit accumulated during the development stage	(18,749,138)	(13,285,180)
Total stockholder's (deficit) equity	(579,374)	2,351,035
Total liabilities and stockholders' (deficit) equity	$ 353,235	$ 2,862,004

The accompanying notes are an integral part of these audited 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, 2007 and 2006,
And for the period of inception
(October 30, 2002) to December 31, 2007

	For the Year Ended December 31,		For the Period October 30, 2002 to December 31, 2007
	2007	2006	
Revenues	$ -	$ -	$ -
Operating expenses:			
Selling, general and administrative expenses	5,516,323	2,445,317	16,085,941
Merger fees and costs	-	-	350,000
Financing cost	-	-	90,000
Impairment of intangible asset costs	-	-	6,393
Total operating expenses	5,516,323	2,445,317	16,532,334
Operating loss	(5,516,323)	(2,445,317)	(16,532,334)
Other expense:			
Cost of penalty for late registration of shares	-	(438,601)	2,192,160
(Gain) loss from marking to market - warrant portion of penalty for late registration of shares	-	(123,505)	(378,198)
(Gain) loss from marketing to market - stock portion of penalty for late registration of shares	-	(445,673)	(760,058)
Interest (income) expense, net	(62,909)	48,508	1,152,356
Total other (income) expense	(62,909)	(959,271)	2,206,260
(Loss) before income taxes	(5,453,414)	(1,486,046)	(18,738,594)
Provision for income taxes	(10,544)	-	(10,544)
Net (loss)	$ (5,463,958)	$ (1,486,046)	$ (18,749,138)
Net income (loss) per share - basic and diluted	$ (0.05)	$ (0.02)	$ (0.38)
Weighted average shares outstanding -basic and diluted	114,221,943	73,234,541	48,979,038

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

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IR Biosciences Holding, Inc. and Subsidiary
(A Development Stage Company)
Consolidated Statement of Stockholders' Equity (Deficit)
From period of inception (October 30, 2002) to December 31, 2007

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Deferred Compensation	Common Stock Subscribed	Accumulated Deficit	Total
Balance at October 30, 2002 (date of inception)	-	$ -	$ -	$ -	$ -	$ -	$ -
Shares of common stock issued at $0.0006 per share to founders for license of proprietary right in December 2002	16,612,276	16,612	(7,362)	-	-	-	9,250
Shares of common stock issued at $0.0006 per share to founders for services rendered in December 2002	1,405,310	1,405	(623)	-	-	-	782
Shares of common stock issued at $0.1671 per share to consultants for services rendered in December 2002	53,878	54	8,946	(9,000)	-	-	-
Sale of common stock for cash at $0.1671 per share in December 2002	185,578	186	30,815	-	-	-	31,001
Net loss for the period from	-	-	-	-	-	(45,918)	(45,918)

inception (October 30, 2002) to December 31, 2002								
Balance at December 31, 2002 (reflective of stock splits)	18,257,042	$ 18,257	$ 31,776	$ (9,000)	$ -	$ (45,918)	$ (4,885)	

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

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IR Biosciences Holding, Inc. and Subsidiary
(A Development Stage Company)
Consolidated Statement of Stockholders' Equity (Deficit)
From period of inception (October 30, 2002) to December 31, 2007
(continued)

	Common Stock		Additional Paid-In	Deferred	Common Stock	Accumulated	
	Shares	Amount	Capital	Compensation	Subscribed	Deficit	Total
Shares granted to consultants at $0.1392 per share for services rendered in January 2003	98,776	99	13,651	-	-	-	13,750
Sale of shares of common stock for cash at $0.1517 per share in January 2003	329,552	330	49,670	-	-	-	50,000
Shares granted to consultants at $0.1392 per share for services rendered in March 2003	154,450	154	21,346	-	-	-	21,500
Conversion of notes payable to common stock at $0.1392 per share in April 2003	1,436,736	1,437	198,563	-	-	-	200,000
Shares granted to consultants at $0.1413 per share for services rendered in April 2003	14,368	14	2,016	-	-	-	2,030

Sale of shares of common stock for cash at $0.2784 per share in May 2003	17,960	18	4,982	-	-	-	5,000
Sales of shares of common stock for cash at $0.2784 per share in June 2003	35,918	36	9,964	-	-	-	10,000
Conversion of notes payable to common stock at $0.1392 per share in June 2003	718,368	718	99,282	-	-	-	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	2,368,130	2,368	(123,168)	-	-	-	(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	-	-	207,457	-	-	-	207,457

December 2003							
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 December 2003	-	-	85,861	-	-	-	85,861
Net loss for the twelve month period ended December 31, 2003	-	-	-	-	-	(1,856,702)	(1,856,702)
Balance at December 31, 2003	23,431,300	$ 23,431	$ 1,035,441	$ -	$ -	$ (1,902,620)	$ (843,748)

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

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IR Biosciences Holding, Inc. and Subsidiary
(A Development Stage Company)
Consolidated Statement of Stockholders' Equity (Deficit)
From period of inception (October 30, 2002) to December 31, 2007
(continued)

	Common Stock		Additional Paid-In	Deferred	Common Stock	Accumulated	
	Shares	Amount	Capital	Compensation	Subscribed	Deficit	Total
Shares granted at $1.00 per share pursuant to the Senior Note Agreement in January 2004	600,000	600	599,400	(600,000)	-	-	-
Shares issued at $1.00 per share to a consultant for services rendered in January 2004	800,000	800	799,200	(800,000)	-	-	-
Shares issued to a consultant at $0.62 per share for services rendered in February 2004	40,000	40	24,760	(24,800)	-	-	-
Shares issued to a consultant at $0.40 per share for services rendered in March 2004	1,051,600	1,051	419,589	(420,640)	-	-	-
Shares issued to a consultant at $0.50 per share for services rendered in March 2004	500,000	500	249,500	(250,000)	-	-	-
Shares sold for cash at $0.15 per share in March, 2004	8,000	8	1,192	-	-	-	1,200
Shares issued at $0.50 per share to	20,000	20	9,980	-	-	-	10,000

consultants for services rendered in March 2004							
Shares issued to a consultant at $0.40 per share for services rendered in March 2004	2,000	2	798	-	-	-	800
Shares issued to consultants at $0.32 per share for services rendered in March 2004	91,600	92	29,220	-	-	-	29,312
Shares to be issued to consultant at $0.41 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	600,000	600	149,400	(150,000)	-	-	-

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

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IR Biosciences Holding, Inc. and Subsidiary
(A Development Stage Company)
Consolidated Statement of Stockholders' Equity (Deficit)
From period of inception (October 30, 2002) to December 31, 2007
(continued)

	Common Stock		Additional Paid-In	Deferred	Common Stock	Accumulated	
	Shares	Amount	Capital	Compensation	Subscribed	Deficit	Total
Shares issued to officer at $0.32 per share for services rendered in April 2004	200,000	200	63,800	-	-	-	64,000
Conversion of Note Payable to common stock at $0.10 per share in May 2004	350,000	350	34,650	-	-	-	35,000
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 $0.20 per share as a due diligence fee in May 2004	125,000	125	24,875	-	-	-	25,000
Shares issued to a consultant at $1.00 per share for services to be rendered over twelve months beginning May	500,000	500	499,500	(500,000)	-	-	-

2004							
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 2004	-	-	17,915	-	-	-	17,915
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 $0.10 for services to be rendered through July 2005	250,000	250	24,750	(25,000)	-	-	-
Shares issued to a consultant in July and September at $0.41 per share for services to be rendered through April 2005	200,000	200	81,800	-	-	-	82,000
Shares issued to a consultant in September at $0.12 to $0.22 for services rendered through September 2004	127,276	127	16,782	-	-	-	16,909
Shares issued in July to September 2004 as interest on note payable	300,000	300	35,700	-	-	-	36,000

Issuance of warrants with notes payable in July and August 2004	-	-	72,252	-	-	-	72,252
Accrued deferred compensation in August 2004 to a consultant for 100,000 shares at $0.10 per share, committed but unissued	-	-	-	(10,000)	-	-	(10,000)
Shares issued in August 2004 at $0.14 to a consultant for services to be performed through October 2004	100,000	100	13,900	(14,000)	-	-	-

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

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IR Biosciences Holding, Inc. and Subsidiary
(A Development Stage Company)
Consolidated Statement of Stockholders' Equity (Deficit)
From period of inception (October 30, 2002) to December 31, 2007
(continued)

	Common Stock		Additional Paid-In	Deferred	Common Stock	Accumulated	
	Shares	Amount	Capital	Compensation	Subscribed	Deficit	Total
Shares issued in August 2004 at $0.125 per share for conversion of $30,000 demand loan	240,000	240	29,760	-	-	-	30,000
Shares issued in August 2004 at $0.16 per share to a consultant for services provided.	125,000	125	19,875	-	-	-	20,000
Shares issued in October 2004 to employees at $0.16 to $0.25 per share	48,804	49	8,335	-	-	-	8,384
Commitment to issue 100,000 shares of stock to a consultant at $0.23 per share for services to be provided through September 2005	-	-	-	(23,000)	-	-	(23,000)
Sale of stock for cash in October at $0.125 per share, net of costs of $298,155	18,160,000	18,160	1,345,763	-	-	-	1,363,923
Value of warrants issued with sale of common stock in October, net of	-	-	607,922	-	-	-	607,922

costs							
Issuance of warrant to officer in October, 2004	-	-	112,697	-	-	-	112,697
Issuance of stock to investment bankers in October 2004 for commissions earned	4,900,000	4,900	(4,900)	-	-	-	-
Conversion of accounts payable to stock in October at $0.125 per share	1,257,746	1,258	107,382	-	-	-	108,640
Value of warrants issued with accounts payable conversions	-	-	48,579	-	-	-	48,579
Conversion of demand loan to stock in October at $0.11 per share	93,300	93	10,170	-	-	-	10,263
Forgiveness of notes payable in October 2004	-	-	36,785	-	-	-	36,785
Issuance of stock to officer and director at $0.125 per share in October for conversion of liability	1,440,000	1,440	122,493	-	-	-	123,933
Value of warrants issued with officer and director conversion of liabilities	-	-	56,067	-	-	-	56,067
Conversion of debt and accrued interest to	6,703,151	6,703	417,514	-	-	-	424,217

common stock at $0.075 to $0.125 per share							
Value of warrants issued with conversion of debt	-	-	191,111	-	-	-	191,111
Conversion of note payable in October into common stock at $0.075 per share	67,616	68	4,932	-	-	-	5,000
Issuance of warrants to note holders in October 2004	-	-	112,562	-	-	-	112,562
Value of shares issued to CFO as compensation	100,000	100	34,900	-	-	-	35,000
Value of warrants issued to members of advisory committees in November and December	-	-	16,348	-	-	-	16,348
Beneficial conversion feature associated with notes payable	-	-	124,709	-	-	-	124,709
Shares issued per conversion of Note Payable - correction	(9,002)	(9)	9	-	-	-	-
Amortization of deferred compensation through December 31, 2004	-	-	-	2,729,454	-	-	2,729,454
	-	-	-	-	-	(5,305,407)	(5,305,407)

Loss for the twelve months ended December 31, 2004							
Balance at December 31, 2004	62,423,391	$ 62,423	$ 7,922,943	$ (169,986)	$ -	$ (7,208,027)	$ 607,353

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

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IR Biosciences Holding, Inc. and Subsidiary
(A Development Stage Company)
Consolidated Statement of Stockholders' Equity (Deficit)
From period of inception (October 30, 2002) to December 31, 2007
(continued)

	Common Stock		Additional Paid-In	Deferred	Common Stock	Accumulated	
	Shares	Amount	Capital	Compensation	Subscribed	Deficit	Total
Sale of shares of common stock for cash at $0.20 per share in March 2005 for warrant exercise, net of costs	6,600,778	6,600	1,184,256	-	-	-	1,190,856
Value of warrants issued to members of advisory committees in March 2005	-	-	137,049	-	-	-	137,049
Deferred compensation in February 2005 to a consultant for 50,000 shares of common stock at $0.65 per share.	-	-	-	(32,500)	-	-	(32,500)
Warrants exercised at $0.05 per share in June 2003	80,000	80	3,920	-	-	-	4,000
Value of warrants issued to members of advisory committee in June 2005	-	-	70,781	-	-	-	70,781
	-	-	32,991	-	-	-	32,991

Value of warrants issued to investors and service providers in June 2005							
Issuance of 232,153 shares of common stock in July 2005 for conversion of notes payable	232,153	232	64,771	-	-	-	65,003
Issuance of 100,000 shares of common stock in August 2005 to a consultant for services provided	100,000	100	9,900	-	-	-	10,000
Value of warrants issued to advisory committee in September 2005 for services	-	-	20,491	-	-	-	20,491
Amortization of deferred comp for the twelve months ended December, 2005	-	-	-	199,726	-	-	199,726
Value of warrants issued in October and December 2005 to investors and service providers	-	-	18,399	-	-	-	18,399
Loss for the year ended December 31,2005					-	(4,591,107)	(4,591,107)
Balance at December 31, 2005	69,436,322	$ 69,435	$ 9,465,501	$ (2,760)	$ -	$ (11,799,134)	$ (2,266,958)

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

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IR Biosciences Holding, Inc. and Subsidiary
(A Development Stage Company)
Consolidated Statement of Stockholders' Equity (Deficit)
From period of inception (October 30, 2002) to December 31, 2007
(continued)

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Deferred Compensation	Common Stock Subscribed	Accumulated Deficit	Total
Issuance of 100,000 shares to officer, previously accrued	100,000	100	41,316	-	-	-	41,416
Value of warrants issued to members of advisory committee in March 2006	-	-	8,399	-	-	-	8,399
Amortization of deferred compensation for the three months ended March 31, 2006	-	-	-	2,760	-	-	2,760
Issuance of common stock in May 2006 to a consultant for services provided	34,464	35	16,162	-	-	-	16,197
Conversion of accrued interest to common stock at $0.125 per share in May, 2006	19,288	19	2,392	-	-	-	2,411
Conversion of accrued interest to common stock at $0.125	16,324	16	2,025	-	-	-	2,041

per share in May, 2006							
Conversion of accrued interest to common stock at $0.10 per share in May, 2006	13,454	14	1,341	-	-	-	1,355
Common stock issued pursuant to the exercise of warrants at $0.09 per share in June 2006	5,000	5	445	-	-	-	450
Value of warrants issued to members of advisory committee in June 2006	-	-	8,820	-	-	-	8,820
Value of warrants issued to members of advisory committee in September 2006	-	-	3,495	-	-	-	3,495
Value of warrants issued to officers	-	-	50,874	-	-	-	50,874
Issuance of penalty Common Stock, previously accrued	4,150,798	4,151	867,514	-	-	-	871,665
Issuance of penalty warrants, previously accrued	-	-	182,239	-	-	-	182,239
Value of options issued to officer	-	-	78,802	-	-	-	78,802

Value of warrants issued to members of advisory committee in December 2006	-	-	1,974	-	-	-	1,974
Issuance of Common Stock for cash	34,266,250	34,267	4,579,282	-	-	-	4,613,549
Common stock to be issued as commission for equity fund raising	-	-	(5,483)	-	5,483	-	-
Value of options issued to officer	-	-	32,120	-	-	-	32,120
Value of options issued to officer	-	-	185,472	-	-	-	185,472
Loss for the year ended December 31, 2006	-	-	-	-	-	(1,486,046)	(1,486,046)
Balance at December 31, 2006	108,041,900	$ 108,042	$ 15,522,690	$ -	$ 5,483	$ (13,285,180)	$ 2,351,035
Common stock issued as commission for equity fund raising	5,482,600	5,483	-	-	(5,483)	-	-
Common stock issued to consultant in January, 2007 at $0.15 per share	298,039	298	44,408	-	-	-	44,706
Common stock issued to consultants in January, 2007 at $0.155 per	400,000	400	61,600	-	-	-	62,000

share							
Common stock issued to consultants in January, 2007 at $0.15 per share	100,000	100	14,900	-	-	-	15,000
Value of options issued to officer in January, February and March 2007	-	-	471,457	-	-	-	471,457
Value of options issued to employee in January, 2007	-	-	5,426	-	-	-	5,426
Value of warrants issued to a consultant in April 2007	-	-	166,998	-	-	-	166,998
Value of options issued to employees in July 2007	-	-	996,133	-	-	-	996,133
Value of options issued to directors in July 2007	-	-	537,833	-	-	-	537,833
Value of options issued to consultants in July 2007	-	-	80,996	-	-	-	80,996
Common stock to be issued for consulting services	-	-	-	-	33,000	-	33,000
Common stock to be issued for finder’s fee	-	-	-	-	120,000	-	120,000
Loss for the year ended	-	-	-	-	-	(5,463,958)	(5,463,958)

December 31, 2007								
Balance at December 31, 2007	114,322,539	$ 114,323	$ 17,902,441	$ -	$ 153,000	$ (18,749,138)	$ (579,374)	

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

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IR BioSciences Holdings, Inc. and Subsidiary
(A Development Stage Company)
Consolidated Statements of Cash Flows for the years
ended December 31, 2007 and 2006,
and for the period of inception (October 30, 2002)
to December 31, 2007

	For the Year Ended December 31,		For the Period October 30, 2002 to December 31,
	2007	2006	2007
Cash flows from operating activities:			
Net loss	$ (5,463,958)	$ (1,486,046)	$ (18,749,138)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash compensation	2,488,843	398,663	6,808,359
Cost of penalty for late registration of shares - stock portion	-	(360,197)	1,631,726
Cost of penalty for late registration of shares - warrant portion	-	(78,404)	560,434
(Gain) from marking to market - stock portion of penalty for late registration of shares	-	(445,673)	(760,058)
(Gain) from marking to market - warrant portion of penalty for late registration of shares	-	(123,505)	(378,198)
Legal fees for note payable	-	20,125	20,125
Placement fees for note payable	-	65,000	65,000
Impairment of intangible asset	-	-	6,393
Interest expense	-	-	156,407
Amortization of discount on notes payable	-	-	1,006,935
Depreciation and amortization	14,916	8,381	52,515
Changes in operating assets and liabilities:			
Deposits	(4,868)	-	(4,868)
Prepaid services and other assets	(6,792)	(38,392)	(41,950)
Accounts payable and accrued expenses	516,346	6,064	1,178,363
Salary advance	(525)	(1,500)	(2,025)
Net cash used in operating activities	(2,456,038)	(2,035,484)	(8,449,980)
Cash flows from investing activities:			
Acquisition of property and equipment	(24,945)	(32,397)	(65,429)
Net cash used in investing activities	(24,945)	(32,397)	(65,429)
Cash flows from financing activities:			
Proceeds from notes payable and cash advances	-	719,875	1,953,375
Principal payments on notes payable and demand loans	(50,000)	(779,750)	(1,094,747)
Shares of stock sold for cash	-	4,613,549	7,873,451
Proceeds from exercise of warrant	-	450	4,450

Officer repayment of amounts paid on his behalf	-	-	19,880
Cash paid on behalf of officer	-	-	(19,880)
Net cash provided by financing activities	(50,000)	4,554,124	8,736,529
Net increase (decrease) in cash and cash equivalents	(2,530,983)	2,486,243	221,120
Cash and cash equivalents at beginning of period	2,752,103	265,860	-
Cash and cash equivalents at end of period	$ 221,120	$ 2,752,103	$ 221,120
Supplemental disclosures of cash flow information:			
Cash paid during the period for:			
Interest	$ 6,000	$ 36,500	$ 86,053
Taxes	$ -	$ -	$ 8,115
Acquisition and capital restructure:			
Liabilities assumed	-	-	(120,799)
Common stock retained	-	-	(2,369)
Adjustment to additional paid-in capital	-	-	123,168
Organization costs	-	-	350,000
Total consideration paid	$ -	$ -	$ 350,000
Common stock issued in exchange for proprietary rights	$ -	$ -	$ 9,250
Common stock issued in exchange for services	$ 230,000	$ 16,197	$ 3,177,483
Common stock issued in exchange for previously incurred debt and accrued interest	$ -	$ 5,807	$ 1,066,401
Common stock issued in exchange as interest	$ -	$ -	$ 36,000
Amortization of beneficial conversion feature	$ -	$ -	$ 223,269
Stock options and warrants issued in exchange for services rendered	$ 2,258,843	$ 347,268	$ 3,378,492
Debt and accrued interest forgiveness from note holders	$ -	$ -	$ 36,785
Common stock issued in satisfaction of amounts due to an Officer and a Director	$ -	$ -	$ 180,000
Common stock issued in satisfaction of accounts payable	$ -	$ -	$ 157,219
Deferred compensation to a consultant accrued in March 2005	$ -	$ -	$ 2,630,761
Amortization of deferred compensation	$ -	$ 2,760	$ 202,486

Fair value of common stock and warrants in payable in connection with late filing of registration statement	$ -	$ 1,053,904	$ 3,684,664
Gain from marking to market - stock portion of penalty for late registration of shares	$ -	$ (805,870)	$ (1,124,255)
Gain from marking to market - warrant portion of penalty for late registration of shares	$ -	$ (201,910)	$ (456,603)
Impairment of intangible asset	$ -	$ -	$ 6,393
Issuance of stock to Officer, previously accrued	$ -	$ 41,416	$ 41,416
Value of warrants issued to members of advisory board			