IR BIOSCIENCES HOLDINGS INC
Form 10KSB
April 17, 2007

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

FORM 10-KSB

x	**Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934** **For the fiscal year ended December 31, 2006**
	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.)
4021 N. 75th Street, Suite 201, Scottsdale, AZ (Address of Principal Executive Offices)	**85251** (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 is not 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 April 5, 2007 (based on the average of the bid and asked prices as reported by the NASD OTC Bulletin Board as of that date) was approximately $12,639,518.

The number of shares outstanding of Registrant's Common Stock, par value $0.001 as of April 5, 2007: 114,318,315.

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

TABLE OF CONTENTS

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 OR PLAN OF OPERATION" 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.

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™. We defined Radilex and Viprovex as derivatives of Homspera due to the potential difference in formulations and indications for use of such compounds. Our goal is to develop these potential drug candidates to be used as possible countermeasures for homeland security threats, including radiological, chemical and biological agents, such as influenza and anthrax. We hope there may exist not only a market for products related to biodefense through governmental purchasing, but there also may exist a potential commercial market for treatments of cancer treatment side-effects and seasonal influenza.

Our patents, patent applications and continued research are 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, these 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 early, 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 the results of our studies 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 on the development of two potential formulations derived from Homspera, Radilex and Viprovex.

We are researching Radilex for use as a potential treatment for acute exposure to radiation. To date we have sponsored seven studies and co-sponsored three studies all of which were conducted utilizing rodents. The results of these studies suggest Radilex may play a role in increased survival among tested rodents following exposure to lethal doses of gamma 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. Based on early studies on Homspera and existing literature on Substance P, we are researching the efficacy of Viprovex as a potential treatment for exposure to chemical agents, such as formalin. To date we have sponsored three studies related to the treatment of influenza, three on the exposure to anthrax spores and one on exposure to formalin. We believe the results of these studies indicated potential efficacy in the use of Viprovex as both a stand alone treatment and an adjuvant, to be used in conjunction with other drugs. 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. 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.

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 filed patent applications and provisional patent applications, for the use of Homspera and derivatives thereof. We own four registered patents, two issued U.S. and two issued foreign patents. We also have 35 pending patents, comprised of four pending Patent Cooperation Treaty (PCT) applications, nine pending U.S. provisional patent applications and 22 pending foreign provisional patent applications.

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

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. 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.

SUBSTANCE P AND HOMSPERA™

Our patents, patent applications and continued research are 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 this research, these scientists created for study a number of analogues, or structural derivatives with slight chemical differences, of 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, a basic building block 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. When components of the nervous system use chemicals to transmit signals between nerves and brain cells to propagate signaling throughout the body, those chemicals are called neurotransmitters. When peptides are released by nerves cells or other cells and modulate this neurotransmission, they are termed neuropeptides.

One such neuropeptide is Substance P. Substance P is a relatively small peptide made of just eleven amino acids. Substance P was discovered in 1931 and found to have local blood-pressure reducing effects. The peptide is difficult to isolate, and consequently was ignored for tens of years. When science developed to the point that peptides could be recognized by their amino acid structures, Substance P was one of the first identified. 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-NH_2.

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 the cells of 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, NK2 and NK3 receptors, and binding of Substance P to one receptor subtype or another will cause different chemical signaling to occur both inside and outside cells. These receptor binding differences are believed to be responsible for the different physiological results following the stimulation of the different receptor subtypes.

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(O_2)) in place of methionine (Met) at the eleventh position. The resulting peptide, still 11 amino acids long, but now with a slightly different molecular weight, is thus called Sar^9, Met $(O_2)^{11}$-Substance P. The amino acid sequence for Homspera is presented below:

Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Sar-Leu-Met(O_2)-NH_2.

It is these specific chemical alterations that are presumably responsible for the different physiological actions of Homspera versus endogenous Substance P. In fact, Sar^9, Met $(O_2)^{11}$-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 Sar^9, Met $(O_2)^{11}$-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 enzyme that usually breaks down Substance P and thereby terminates its action. Thus Sar^9, Met $(O_2)^{11}$-Substance P is both more specific than Substance P, and also more persistent in the body.

In December 2004 we filed an application with the US Patent and Trademark Office in an effort to trademark the name Homspera to refer to Sar^9, Met $(O_2)^{11}$-Substance P for its potential usage in a number of applications. Our application is still pending.

Radilex™ and Viprovex™

We use the trade names Radilex and Viprovex to differentiate these 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 treatments, and thus have different indications for use, we anticipate that we will formulate them differently in the future to 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 thus applications, with respect to their development and potential future market opportunities.

In the early AFOSR studies, 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 having 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.

Based on our interpretation of these results, our current focus is on the development of two potential drug applications, Radilex and Viprovex.

We are researching Radilex for use as a potential treatment for acute exposure to radiation. To date we have sponsored seven studies and co-sponsored three studies all of which were conducted utilizing rodents. 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 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 treatments.

Viprovex is being researched by us for use in potential treatments of exposure to biological agents, such as anthrax and infectious diseases, including influenza. 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. To date we have sponsored three studies related to the treatment of influenza, three on the exposure to anthrax spores and one on exposure to formalin. We believe the results of these studies indicated potential efficacy in the use of Viprovex as both a stand alone treatment and to be used in conjunction with other drugs. 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. 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 existing drugs.

Applications

Our initial pre-clinical applications that we are researching are in the treatment of the effects on the body caused by (i) exposure to radiation (Radilex) (ii) infectious disease and harmful biological materials (Viprovex) and (iii) harmful chemical agents (Viprovex). In addition to these three 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.

To date we have sponsored seven radiation studies and co-sponsored three radiation studies all of which were conducted utilizing rodents. We have sponsored three studies on the potential treatment of anthrax exposure and one study on avian influenza all of which were conducted utilizing rodents. We have also sponsored one chemical study in an attempt to determine initial indications of efficacy on the treatment of formalin exposure.

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 for the potential use of Radilex in the treatment of acute radiation syndrome and one 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	Pharmacological Identification	Animal Safety	Pre-Clinical Mechanistic	Phase I	Phase II	Phase III
Acute Radiation Syndrome						
Radilex	In-progress	In-progress	In-progress			
Infectious disease						
Viprovex	In-progress	In-progress	In-progress			
Chemical exposure						
Viprovex	In-progress	Planned	In-progress			

The preliminary results of our pre-clinical studies using 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."

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 (PIND) number for the use of Radilex (PIND No. 63,255) in the treatment of acute radiation syndrome.

To date we have sponsored seven radiation studies and co-sponsored three radiation studies all of which were conducted utilizing rodents to study dose response to radiation, the impact on survival and to distinguish survival response using different forms of drug delivery. In each of these studies mice were exposed to varying levels of radiation.

Radiation is emitted electromagnetic energy. Excessive exposure to ionizing radiation over a short period of time, as is the case in nuclear or radiological attacks, leads to the development of radiation sickness, or Acute Radiation Syndrome (ARS). Exposure to lower doses of radiation may, either by design 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, which are vital for the formation of blood clots, in the circulation, resulting in compromised oxygen carrying capacity, diminished immune system function, and uncontrollable bleeding.

These bone marrow cells are called hematopoietic stem cells, and they can multiply and mature into precursor cells to the B-cells and T-cells of the immune system, or into precursors of the red blood cells and of the granulocytes and macrophages, which are also of the immune system, and megakaryocytes, which produces platelets. Thus all circulating cells of the immune system, red blood cells and platelets derive from these stem cells.

In studies to date we have collected data that we believe suggests that Radilex shows efficacy in treating ARS by combating neutropenia and thrombocytopenia, which is the decrease in blood levels of white blood cells and platelets, the major medical conditions associated with acute exposure to radiation. Loss of these cells results in increased sensitivity to infection and to uncontrolled bleeding, both of which can be potentially life-threatening. Further, as treatment for cancer often includes radiation treatment, we believe that the potential also exists for Radilex to be used for cancer patients as a stand alone treatment or a co-therapeutic agent to be used with other drugs as treatment.

Data collected in studies performed at the Oak Ridge National Laboratory in 2006, we believe, revealed that Radilex not only prolonged survival of animals exposed to lethal gamma irradiation, but also appeared to have increased platelet concentrations in surviving animals.

There is also preliminary research data showing that the activity of a specific enzyme (poly-(ADP-ribosyl) polymerase, or PARP), may be responsible for repairing DNA that has been damaged by radiation can be modified by Substance P. When damage is severe, the activation of this enzyme becomes too much for the cell to support, and the cell triggers its own destruction. The chain of events that result in this destruction is called apoptosis, a process of deliberate life termination that a cell undergoes following exposure to high levels of stress, and agents that can control the rate of apoptosis are of significant importance in controlling the functioning of organs and organisms. If a cell can be kept alive long enough to repair cellular damage, it might be of more value to the organism.

Based on the above referenced, and other, data, we believe that one possible mechanism by which Radilex is able to prolong survival in animal models (either in addition to its effect on stem cells or perhaps as a mechanism by which it impacts stem cells), is by modulating the activities of the PARP-1 enzyme within cells.. By possibly preventing cells from dying, Radilex may be effective in treating the impact of cell radiation, thereby decreasing the likelihood of death.

Further, we believe that our survival data from irradiated mice studies and mechanistic studies in cell culture have shown indications of hematopoietic stem cell replenishment of circulating leukocytes and platelets, which could be of value in radiation-treated cancer patients.

Acute total body irradiation exposure studies have been performed at the University of Arizona Cancer Center and at Oak Ridge National Laboratories (ORNL). These studies show that radiation destroys the immune system resulting in pneumonia and death, and that Radilex, we believe demonstrates efficacy at reversing the loss of white blood cells that comprise the immune system, as well as platelets necessary to control blood clotting, subsequently leading to an increase in survival rates.

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, such as formalin. Formalin, a highly toxic chemical, is a solution of formaldehyde gas dissolved in water and used industrially.

Biological Exposure Applications

Infectious Disease - Seasonal and Pandemic Influenza

We believe of management 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 AFOSR 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 washing lavage the lungs 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, opening up 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 three influenza studies conducted at Virion Systems, Inc, one of which is still ongoing, utilizing rodents to test the efficacy of Viprovex in treating the avian influenza A/Wuhan/359/95 (H3N2), a model system for studying the H5N1 avian influenza.

In our opinion, the data acquired to date in 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) such as certain interleukins and interferons were also witnessed. In the opinion of management, such Viprovex-induced changes in immune response as evinced 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) are neuraminidase inhibitors) to treat influenza (by inhibiting an enzyme necessary for infectivity), Viprovex might be an effective adjuvant therapeutic on treating or preventing influenza.

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

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%. In contrast, the inhalation of *B. anthracis* spores results in a significantly more severe and lethal infection, with mortality rates of greater than 80%. As a result of the high mortality rate and route of infection, anthrax is considered a prominent agent of bioterrorism.

To date we have sponsored three anthrax studies all of which were conducted utilizing rodents to determine if Viprovex will reduce the mortality rate of an active infection of pulmonary anthrax. In our opinion, when treated with Viprovex prior to exposure to anthrax spores, Viprovex elicited protective, prophylactic efficacy and when treated a short time period after exposure to anthrax spores, Viprovex elicited therapeutic efficacy.

In 2006 we completed a series of studies with Hyperion Biotechnology Inc. at their laboratory facilities located at Brooks City-Base in San Antonio, Texas. The purpose of these studies was to determine if Viprovex could reduce the mortality rate of an active infection of pulmonary anthrax. The first of these studies was initiated in October 2005. This research indicated, in our opinion, that Viprovex offers protection from anthrax exposure in a mouse model. In these studies, we witnessed mice treated with Viprovex to have a greater survival rate 11 days post-exposure to anthrax spores. Additionally, based on this research, we believe Viprovex to elicit a prophylactic protection from anthrax in a mouse model.

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, when used as an adjuvant, 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 March 2007, we began the first of a series of studies to investigate the therapeutic effects of Viprovex on acute melioidosis. These studies are to be performed in conjunction with Singapore's Defense Medical & Environmental Research Institute, DSO National Laboratories ("DSO"). The studies are to be funded by DSO and are expected to be completed during the third quarter of 2007.

Chemical Exposure Applications

Based on early studies on Homspera and existing literature on Substance P, we are researching the efficacy of Viprovex as a potential treatment for exposure to chemical agents, such as formalin. Formalin is a solution of formaldehyde gas dissolved in water, used industrially and toxic typically via crosslinking of proteins to other nearby proteins. 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.

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 immune system effects, while administration of Substance P antagonists compounded the deleterious effects. Further experiments performed using Viprovex examined effectiveness in preventing lung injury on inhalation of toxic fumes. In our opinion based on our results, Viprovex has been shown to exhibit anti-inflammatory effects in animal models.

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

Formalin

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 efficacious in attenuating lung injury after formalin exposure.

In rats exposed to an aerosol application of formalin data suggests, in our opinion, that treatment with 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.

ADJUVANT THERAPEUTIC

Results from studies also suggest that Homspera may also have potential value as a co-therapeutic agent or vaccine adjuvant. Studies performed in animal models of influenza and acute radiation syndrome have revealed the potential capability of Homspera to enhance the action of approved anti-viral medications as well as to provide adjunctive impact on anti-tumor radiation therapy.

Adjuvants are unique among active ingredients in drugs in that they are designed to not stimulate an immune response against themselves, but they are required to augment the immune response against other, co-administered compounds.

The potential efficacy of Homspera as a vaccine adjuvant results from the unique mechanism through which Homspera modulates the immune system. The actions of Homspera are mediated predominately through interactions with the Neurokinin-1 receptor (NK1-R).

Studies in cell culture have revealed elevations in components of what is the most basic aspect of the immune system, termed the innate immune system, that are consistent with activation of specific cell components called Toll-like Receptors, a postulated mechanism by which vaccine adjuvants increase immune responses to vaccine components.. Additionally, the anti-anthrax activity reported by Homspera 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, in conjunction with other influenza therapeutics,, Homspera might be an effective adjuvant therapeutic by decreasing the number of viruses at which the viral neuraminidase-targeted therapeutic must act.

We believe that there is also potential for Homspera to be used as a co-therapy to what is called adjuvant therapy for cancer patients, as secondary treatment often involves radiation treatments following chemotherapy, in an attempt to kill more of the cancer cells. Survival data from gamma-irradiated mice studies have shown indications of hematopoietic stem cell replenishment of circulating leukocytes and platelets, which could be of value in radiation-treated cancer patients. There is no assurance that our interpretation of the results of the studies will prove to be accurate after further testing.

POTENTIAL FUTURE PIPELINE APPLICATIONS

During our research and development efforts, we may, from time to time, observe results that may lead to other potential applications using Homspera. At the time of such an observation, we may design studies to further evaluate the use for the indication. If these further studies support our initial observations, we may file provisional patent

applications for the use of Homspera with the hope of protecting future development rights until we have the ability to design additional studies and protocols and perform research with regard to such applications.

To date, we have filed use patent applications in multiple jurisdictions, inside and outside of the U.S., for use of the active ingredient in Homspera for: treatment of avian influenza in mammals, reducing the risk or severity of anthrax infection, treatment of blood cell depletion, ameliorating or preventing damage caused by cigarette smoke, for treating patients with SARS (Severe Acute Respiratory Syndrome) or ARDS (Acute Respiratory Distress Syndrome) or to prevent those exposed to their causative agents, for inducing new hair growth or retarding hair loss, for reducing certain ageing effects, such as interrupted sleep patterns, residual muscle pain, short term memory loss, diminished visual accommodation, decreased muscle strength, and arthritic pain, for stimulating wound healing in a radiation-exposed mammal, for treating asthma, for treating skin diseases, in particular, eczema, psoriasis, acne, and basal cell carcinoma, for prophylactically treating domestic fowl to prevent respiratory infections, and for maintaining or inducing hair color. To date, our development activities in these areas have been limited to only small pilot exploratory studies in order to observe and collect data that would justify filing use patent applications. In the future, we may choose to conduct additional research and development to further our observations in these areas.

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 $484,029 and $237,005 in 2006 and 2005, respectively, in research and development activities related to the development of Radilex and Viprovex as protectants against the effects of biological and radiological/nuclear threats. From our inception in October 2002, we have spent $1,026,597 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 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 $700,000 in an effort to further develop Radilex and Viprovex. This research and development cost estimate includes additional animal pharmacology studies, formulation and animal safety/toxicity studies. 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 eleven 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.

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, we intend to 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.

Contract Research Organizations (CRO) and Collaborators

It is understood that extensive time and money is spent developing new drug applications by the time they are approved by required 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 Contract Research Organizations (CRO's) and collaborative relationships.

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.

In addition, we have fostered and managed relationships with other laboratories working in related areas of research and government agencies who are interested in learning more of our applications, and perhaps helping to bring them to commercialization.

Collaborators and Contractors who we have already worked with or are implementing a program with are described below.

- University of Arizona College of Medicine, Tucson, Arizona. We have sponsored or co-sponsored seven mouse radiation studies and co-sponsored one inhalation study at the University of Arizona College of Medicine, Tucson, Arizona since January, 2005. In addition, the Air Force Office of Scientific Research, AFOSR, has sponsored additional studies at the University of Arizona College of Medicine utilizing Homspera, Radilex and Viprovex.

    - Hyperion Biotechnology Inc. Hyperion Biotechnology performs research programs in the areas of probiotics, biomarker discovery, infectious disease and human performance enhancement. We have contracted a series of anthrax studies with Hyperion testing Viprovex as a potential treatment to anthrax infection. These studies are conducted by Hyperion at its research facility located on the U.S. Air Force School of Aerospace Medicine (USAFSAM) campus in Brooks City-Base in San Antonio, Texas. To date we have completed three studies on anthrax. Hyperion has also conducted mechanistic studies in cell culture looking at cellular mechanisms impacted by Homspera. These studies are ongoing.

- St. Joseph's Hospital and Medical Center (Phoenix, Arizona). St. Joseph's has performed assays on Homspera for us on a sub-contracting basis.

- Battelle Memorial Institute's Medical Research and Evaluation Facility (MREF) (Columbus, Ohio). Battelle has issued a letter of intent to support us in our testing of Homspera as an Avian Influenza therapeutic in mice. Battelle is actively involved in analytical development studies through activities at PNNL and studies protocols are in development for avian influenza studies that may be initiated at Battelle.

- Pacific Northwest National Laboratory (Richland, Washington). PNNL has issued a letter of intent to support us in our testing of Homspera as a Universal Protectant therapeutic. In addition to ongoing analytical studies at PNNL and managed by Battelle, additional studies regarding radiation and influenza in both small animals and non-human primates, are under discussion and protocols are being developed.

- Oak Ridge National Laboratory (Oak Ridge, Tennessee). We have contracted with Oak Ridge to conduct Proof of Concept mouse radiation studies that began in February, 2006 and to help facilitate additional pre-clinical and future clinical trials with regard to testing Radilex for potential uses to treat the effects of acute radiation. To date, we have completed three studies that have confirmed experimental results obtained previously and have expanded insight into radioprotection dosing and mechanisms.

- PanFlu LLC and Virion Systems, Inc. We have contracted with PanFlu and Virion to conduct influenza studies to test the efficacy of Viprovex in treating the avian influenza A/Wuhan/359/95 (H3N2), a model system for studying the H5N1 avian influenza. To date two completed studies have provided evidence that we believe suggests viral reduction by Viprovex and provided preliminary evidence for potential mechanisms. Planned studies include a co-treatment study with the neuraminidase inhibitor oseltamivir (Tamiflu®, Roche).

    - TGen (Translational Genomics Research Institute) Drug Development Services (TD2 LLC) (Phoenix, Arizona). We have contracted with TGen to perform anti-cancer research designed to assess preclinical safety and efficacy (with the ability to expand to Phase 1 and Phase 2a clinical studies at the associated Mayo Clinic Scottsdale, MD Anderson Cancer Center and Arizona Cancer Center Tucson). A broad spectrum of Preclinical Studies are ongoing at TD2, including cancer screening against established cell lines and chemo-therapeutics, analytical assay development, radioprotection studies in small animals and non-GLP safety and pathology studies.

        - AAIPharma. We have contracted with AAIPharma to do analytical development work.

- GenPhar, Inc. We have contracted with GenPhar to perform adjuvant studies in mice in conjunction with their vaccine platform technology.

- Singapore's Defense Medical & Environmental Research Institute, DSO National Laboratories. We have contracted with Singapore's Defense Medical & Environmental Research Institute, DSO National Laboratories to perform a series of studies to investigate the therapeutic effects of Viprovex on acute melioidosis. The first in the series of studies began in March 2007.

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.

Consultants

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

Kelly McQueen, MD, MPH, PLLC was engaged in July 2005 to provide comprehensive public health consulting and act as liaison with United States military services to pursue collaborative research in the area of infectious diseases and upper respiratory illnesses. Dr. McQueen is a practicing anesthesiologist and public health consultant in Phoenix, Arizona. She currently works with the United States (U.S.) Army and the US Northern Combatant Command on Infectious Disease, Disaster Planning and other public health projects. Dr. McQueen also teaches infectious disease threat management and treatment for the International Committee for the Red Cross (ICRS) course on Health Emergencies in Large Populations (HELP). Dr. McQueen's contract with us provides for cash compensation on an hourly basis and reimbursement for travel and expenses. The original term of the agreement was until October 2005 but has been mutually agreed to have been extended on the same terms on a month by month basis.

Dr. Jack Caravelli, Ph.D. was contracted in November 2005 to provide advisory services in support of our initiative to commercialize radiation sickness treatments, bio-defense applications and countermeasures. He is presently a senior advisor for the Threat Reduction Cooperation with the Office of Policy at the U.S. Department of Energy (D.O.E.). Dr. Caravelli's contract provides for cash compensation at an hourly rate and reimbursement for any related travel and expenses. The original term of the agreement was until January 2006 but has been mutually agreed to have been extended on the same terms on a month by month basis.

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 warrants.

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. Dr. Dann is a graduate of Harvard University Dental School and Washington University Medical School. He is a 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.

Sarah A. Kagan, J.D., Ph.D. Sarah Kagan is a partner in the Banner & Witcoff, Ltd., an intellectual property legal firm in Washington, D.C. Dr. Kagan holds a Ph.D. degree in molecular biology from the University of Wisconsin (1981) and a J.D. degree from George Washington University (1988). Dr. Kagan’s professional memberships include the American Bar Association, Women’s Bar Association of the District of Columbia, and the American Intellectual Property Law Associations.

Susan E. Leeman, Ph.D. Dr. Leeman is a 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.

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.

Akihiro Shimosaka, Ph.D. Dr. Shimosaka has extensive domestic and international experience in consulting early and later stage biotechnology companies in research and development, product development and regulatory issues.

Dr. Hal Siegel Ph.D., Dr. Siegel has two decades of experience providing scientific, clinical and regulatory assistance to life science client companies across the medical product spectrum, helping them meet business needs and FDA requirements from pre-clinical studies through the regulatory submission process and into the post-approval marketplace. Dr. Siegel is a member of our Board of Directors and serves as our Senior Director, Product Development and Regulatory Affairs.

The Bioterrorism Preparedness Advisory Board was formed at the suggestion of the U.S. Food and Drug Administration's (FDA) Division of Counterrorism (DCT) to develop a "response team" that can be rapidly deployed to an incident site in the event of a biological or radiological attack to help in implementation, conduct and data acquisition. As there are several first responder teams already in place, we opted to concentrate on forming a group to discuss logistics and coordination between agencies and these first responder groups in the event of an attack. 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., Senior Advisor: Captain, United States Navy, Medical Corps, Naval Medical Center, San Diego, Pulmonary Medicine

Jack Caravelli, Formerly Senior Advisor to the Department of Energy for Threat Reduction Cooperation

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

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

Mr. Michael Deutsch, Associate Advisor: Homeland Security Liaison, Principal, Immediate Solutions, LLC

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

The Honorable Asa Hutchinson, J.D. Senior Advisor: former Under Secretary for Border and Transportation Security at the Department of Homeland Security, Partner and chair of Venable LLP's Homeland Security Group.

Elizabeth Ceilley Hyslop, M.D., Associate Advisor: Clinical Practitioner, Durango Cancer Center.

John Kalns Ph.D.: Vice President and Chief Scientific Officer Hyperion Biotechnology, Inc. at Brooks City-Base.

Col. Kerrie Lindberg (Ret.), Associate Advisor: 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.

We have used and expect to continue to use third party manufacturers to obtain synthetic Homspera or Sar^9, Met $(O_2)^{11}$-Substance P, the active ingredient in experimental formulations of Radilex and Viprovex. We believe Sar^9, Met $(O_2)^{11}$-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 Sar^9, Met

$(O_2)^{11}$-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 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.

PATENTS AND PROPRIETARY RIGHTS

Patents and other proprietary rights are essential to our business. We file patent applications to protect our technologies, 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 and provisional patent applications for the use of Sar^9, Met $(O_2)^{11}$-Substance P, the active ingredient in Homspera, Radilex and Viprovex. The intellectual property owned by us, as further described below, is for various potential uses of Sar^9, Met $(O_2)^{11}$-Substance P. We own four registered patents, comprised of two issued U.S. and two issued foreign patents. We also have 35 pending patents relating to the use of Sar^9, Met $(O_2)^{11}$-Substance P. These pending patents are comprised of four pending Patent Cooperation Treaty (PCT) applications, nine pending U.S. provisional patent applications and 22 pending foreign provisional patent applications. Additionally, we are in the process of pursuing several other use patent applications based on the use of Homspera.

We currently hold issued patents in the U.S. for use of Sar^9, Met $(O_2)^{11}$-Substance P, the active ingredient in Homspera, Radilex, and Viprovex for inhibiting tumor growth and/or metastasis in cancer patients and for stimulating the immune system of immunocompromised individuals such as Acute Radiation Syndrome victims. Similar patent rights are held in Europe and Australia. In the latter two regions, we also have been issued patent rights for use of the active ingredient in Homspera, Radilex and Viprovex for stimulating the maturation of a juvenile immune system, for stimulating an immune response to a viral or bacterial infection, and for reducing the risk of cancer.

We have also filed patent applications in many jurisdictions, inside and outside of the U.S., for use of the active ingredient in Homspera, Radilex and Viprovex for treatment of avian influenza in mammals, reducing the risk or severity of anthrax infection, treatment of blood cell depletion, ameliorating or preventing damage caused by cigarette smoke; for treating patients with SARS (Severe Acute Respiratory Syndrome) or ARDS (Acute Respiratory Distress Syndrome) or to prevent these conditions in those exposed to putative causative agents; for inducing new hair growth or retarding hair loss; for reducing certain aging effects, such as interrupted sleep patterns, residual muscle pain, short term memory loss, diminished visual accommodation, decreased muscle strength, and arthritic pain; for stimulating wound healing in a radiation-exposed mammal; for treating asthma; for treating skin diseases, in particular, eczema, psoriasis, acne, and basal cell carcinoma; for prophylactically treating domestic fowl to prevent respiratory infections, and for maintaining or inducing hair color. Because these applications have not yet been granted, the rights in these subject matters remain potential.

The following is a list of the registered patents and provisional patent applications in our portfolio. All of the inventor rights for all patents and all patent applications listed have been assigned to us by the inventors. 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 rights to the invention from the United States Air Force and the University of Arizona in regard to patent and patent applications for Substance P Treatment for Immunostimulation. We are expecting to receive similar waivers from the United States Air Force and the University of Arizona for the remaining patent applications in our intellectual property portfolio.

In total, our patent portfolio consists of four registered patents, two issued U.S. and two issued foreign patents. We also have 35 pending patents, comprised of four pending Patent Cooperation Treaty (PCT) applications, nine pending U.S. provisional patent applications and 22 pending foreign provisional patent applications. The assignment documents are included as Exhibits.

Registered Patents:

Title	**Country**	**Registration No.**

Substance P Treatment for Immunostimulation	United States of America	5,998,376
Substance P Treatment for Immunostimulation	United States of America	5,945,508
Substance P Treatment for Immunostimulation	Australia	737201
Substance P Treatment for Immunostimulation	Canada	0957930
	Switzerland	0957930
	Germany	0957930
	Spain	0957930
	France	0957930
	United Kingdom	0957930
	Ireland	0957930
	Italy	0957930
	Liechtenstein	0957930
	Monaco	0957930

Patents Pending:

Title	**Country**	**Application No**.
Method to Promote Wound Healing	Patent Cooperation Treaty	PCT/US05/38646
Prevention of Respiratory Infections in Fowl	Patent Cooperation Treaty	PCT/USO5/42601
Treatment of Skin Diseases	Patent Cooperation Treaty	PCT/US05/45369
Treatment for Asthma	Patent Cooperation Treaty	PCT/US06/11833
Amelioration of Effects of Cigarette Smoke	United States of America	10/645839
Stimulation of Hair Growth	United States of America	10/539734
Acute Respiratory Syndromes	United States of America	10/553232
Inducing and Maintaining Hair Color	United States of America	tba
Anti-Aging Effects of Substance P	United States of America	tba
Method to Reduce the Risk and/or Severity of Anthrax Infection	United States of America	60/828723
Method to Treat Blood Cell Depletion	United States of America	60/809391
Prophylactic and Therapeutic Treatment of Mammals for Avian Influenza Infections	United States of America	60/866901
Use of Homspera (substance P analog) as an adjuvant	United States of America	60/885562

Prevention of Respiratory Infections in Fowl	Singapore	200500467-6
Prevention of Respiratory Infections in Fowl	Thailand	97659
Prevention of Respiratory Viral Infection in Fowl	Vietnam	1-2005-00599
Treatment of Skin Diseases	Singapore	200500466-8
Treatment of Skin Diseases	Vietnam	1-2005-00598
Treatment of Skin Diseases	Thailand	98080
Treatment of Asthma	Singapore	200504104-1
Amelioration of Effects of Cigarette Smoke	Singapore	200501072-3
Amelioration of Effects of Cigarette Smoke	China	3820184.4
Amelioration of Effects of Cigarette Smoke	Japan	2004-532943
Amelioration of Effects of Cigarette Smoke	European Patent Office	3791722.6
Amelioration of Effects of Cigarette Smoke	Canada	2496447
Amelioration of Effects of Cigarette Smoke	Vietnam	1-2005-00215
Acute Respiratory Distress Syndrome	Hong Kong	6107144.4
Acute Respiratory Syndrome	European Patent Office	4759500.4
Acute Respiratory Syndromes	Singapore	200507608-8
Medicaments for Treating or Protecting SARS or ARDS	Vietnam	1-2005-01560
Anti-Aging Effects of Substance P	Japan	tba
Anti-Aging Effects of Substance P	Canada	PCT/US05/13113
Anti-Aging Effects of Substance P	European Patent Office	5755488.3
Anti-Aging Effects of Substance P	China	tba
Anti-Aging Effects of Substance P	Australia	2005240026

Our rights to the US Patent Nos. 5,945,508 and 5,998,376, Substance P Treatment for Immunostimulation, have 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, 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. 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 under such inventions for any governmental purpose. In addition, the government has the right to require us to grant an exclusive license under any of such inventions 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 the patents (US Patent Nos. 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 USC 202(c)(4) and 37 CFR 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.

Moreover, 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. Since patent applications in the U.S. are maintained in secrecy until shortly before a patent's issuance, we also cannot be certain that others did not first file applications for inventions covered by our pending patent applications, nor can we be certain that we will not infringe any patents that may be issued to others on such applications.

We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements. It is our policy to require our employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting 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 not conducted freedom of use patent searches and 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 products or maintain our competitive position with respect to our products. 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 products 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 December 9, 2004 we filed for trademarks with US Patent and Trademark Office (USPTO) for Homspera, Radilex and Viprovex.

On August 15, 2006, Viprovex became a federally registered trademark (Reg. No. 3,130,407) in International Class 5 for pharmaceutical products, namely antidotes for the treatment of viral, chemical and biological warfare agents.

On October 17, 2006, opposition to the Homspera mark was filed by another pharmaceutical company that distributes an anti-viral compound under a name which they claim has a "similar sound and appearance." The matter is currently being negotiated and we have granted an extension of the opposition term.

On December 5, 2006, the Trademark Office issued a Notice of Allowance to our Intent-to-Use (ITU) trademark application for Radilex as biopharmaceuticals, namely products for counteracting exposure to radiation and chemical agents. As of the date of this report, the time for opposition to the Radilex mark has expired.

On January 9, 2007, the Trademark Office issued a Notice of Allowance of our Intent-to-Use (ITU) trademark application for ImmuneRegen for biotechnology pharmaceuticals, namely adjuvants, counteractants and immunostimulant products for enhancing the natural and reactive immunity to toxic agents.

RESEARCH AND LICENSE AGREEMENTS

Our patents and continued research on Sar^{9}, Met $(O_2)^{11}$-Substance P are derived from discoveries made during research studies funded by the Air Force Office of Scientific Research (AFOSR) 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.

GOVERNMENTAL REGULATION

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

REGULATORY PROCESS IN THE UNITED STATES

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

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

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

PRODUCT APPROVAL IN THE UNITED STATES

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

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.

As described above, 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 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.

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.

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 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 NASD OTC Bulletin Board, have recently issued new requirements and regulations and are currently developing additional regulations and requirements in response to recent laws enacted by Congress, most notably the Sarbanes-Oxley Act of 2002. As certain rules are not yet finalized, we do not know the 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.

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. We intend to offer for sale these applications to various governmental agencies at the local, state and federal levels, both domestically and potentially outside the United States.

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., Hollis-Eden Pharmaceuticals, Inc. and Cleveland Biolabs, Inc. have developed or are developing products for treating aspects of severe acute radiation injury. Companies such as VaxGen, Inc., Acambis plc and Emergent BioSolutions 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, 2006, we have relied on the services of outside consultants for services and currently have six total employees; one contract employee, four full-time employees and one part-time employee. 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; and, the fourth 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.

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. Most of our consultants and employees and several of our executive officers began working for us recently, and all employees are subject to "at will" employment. 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.

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, 2006, we had working capital of $2,320,533. This amount consists of cash of $2,752,103 and prepaid services of $79,399 less accounts payable and accrued liabilities of $460,969, and notes payable of $50,000. We have incurred a net loss of $13,285,180 for the period from our inception in October 2002 to December 31, 2006, 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, 2006 and December 31, 2005 was $1,486,046 and $4,591,107 respectively. As of December 31, 2006, we had an accumulated deficit of $13,285,180.

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 $1,486,046 and $2,035,484, respectively, for the year ended December 31, 2006. 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 January 2008. 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 $2.5 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.

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 January 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 $2.5 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 (NDA), and it is subsequently approved, we will not be able to market or manufacture any products.

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

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 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.

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. As a result, 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 Radilex and Viprovex, which are potential drug candidates derived from Homspera. All drug candidates require U.S. Food and Drug Administration ("FDA") 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.

Our current potential drug candidates, Radilex and Viprovex, 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, Radilex and Viprovex, 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 Radilex and Viprovex although there may be no assurance that we will be successful in so doing.

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

The results of our pre-clinical studies may not be indicative of future pre-clinical or clinical trial results. A commitment of substantial resources to conduct time-consuming research, pre-clinical studies and clinical trials will be required if we are to develop any products. Delays in planned patient enrollment in our clinical trials may result in increased costs, program delays or both. None of our potential products or technologies may prove to be safe or effective in clinical trials. Approval of the FDA, or other regulatory approvals, including export license permissions,

may not be obtained and even if successfully developed and approved, our potential products may not achieve market acceptance. Any potential products resulting from our programs may not be successfully developed or commercially available for a number of years, if at all.

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

The market for treating aspects of acute radiation syndrome and exposure to various chemical and biological agents is uncertain and if we are unable to successfully commercialize Radilex or Viprovex, we will not recognize a significant portion of our future revenues, if any.

We do not believe any drug has ever been approved and commercialized for the treatment of severe acute radiation injury. In addition, the incidence of large-scale exposure to nuclear, radiological or biological agents has been low. Accordingly, even if Radilex, our current drug candidate to treat aspects of acute radiation syndrome (ARS) and Viprovex, our drug candidate to treat exposure to various biological agents, are approved by the FDA, we cannot predict with any certainty the size of the markets for them, if any. The potential market for Radilex and Viprovex is largely dependent on the size of stockpiling orders, if any, procured by the U.S. and foreign governments. While a number of governments have historically stockpiled drugs to treat indications such as smallpox, anthrax exposure, plague, tularemia and certain long-term effects of radiation exposure, we are unaware of any significant stockpiling orders for drugs to treat ARS.

To date, although we have filed formal responses to governmental grants, Request for Information (RFI) and Request for Proposal (RFP) for therapeutics to treat ARS and exposure to various chemical and biological agents, none have resulted in funding, stockpiling orders or a commitment to purchase our potential products, if any. Additionally, we cannot guarantee that our response to any future RFI, RFP or other grant application will result in funding, stockpiling orders or a commitment to purchase our potential products, if any.

Any decision by the U.S. Government to enter into a commitment to purchase Radilex or Viprovex prior to FDA approval is largely out of our control. Our development plans and timelines may vary substantially depending on whether we receive such a commitment and the size of such commitment, if any. In addition, even if Radilex or Viprovex is approved by regulatory authorities, we cannot guarantee that we will receive any stockpiling orders for Radilex or Viprovex, that any such order would be profitable to us or that Radilex or Viprovex will achieve market acceptance by the general public.

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, 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 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 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 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.

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

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

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

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 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.

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 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 Radilex and Viprovex used in our studies to date. We may not successfully arrange for contract manufacturing of 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.

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 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 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 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 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 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 own two issued U.S. and two issued foreign patents. We also have 35 pending patents relating to the use of Sar^{9}, Met $(O_2)^{11}$-Substance P, comprised of four pending Patent Cooperation Treaty (PCT) applications, nine pending U.S. provisional patent applications and 22 pending foreign provisional patent applications.

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.

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 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.

Our potential products 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 insurance policy on Mr. Wilhelm and Dr. Siegel for $1,000,000 and $250,000 respectively, payable to the company, on their lives. While we have entered into employment agreements with Mr. Wilhelm and Dr. Siegel, the loss of any of their services would be detrimental to us and could have a material adverse effect on our business, financial condition and results of operations.

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 the NASDAQ Stock Market. 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 have the right to register securities for resale that they hold pursuant to registration rights agreements. We agreed to register an aggregate of 51,399,375 shares of our common stock and shares of common stock underlying purchase warrants that we issued in a private placement that closed in December 2006. We must file the registration statement between June 3, 2007 and June 13, 2007. 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.

The registration and subsequent sales of shares of our common stock will likely have an adverse effect on the market price of our common stock. From time to time, certain stockholders of our company 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 Act ("Rule 144"), subject to certain limitations. In general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who has satisfied a one-year holding periods may, under certain circumstances, sell within any three-month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of our common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitations, by a non-affiliate of our company who has satisfied a two-year holding period. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have an adverse effect on the market price of our securities.

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.

The liquidity of our securities and our obligations to register securities will be impacted by the sec's review of the resale registration statement that we will file.

We closed a private placement of securities on December 6, 2006 pursuant to which we agreed to register 31,399,375 shares of common stock. We intend to file a resale registration statement on Form SB-2, or some other available form, to register for resale such shares of Common Stock. We cannot control this future registration process in all respects as some matters are outside our control. Even if we are successful in causing the effectiveness of the resale registration statement, there can be no assurances that the occurrence of subsequent events may not preclude our ability to maintain the effectiveness of the registration statement. Any of the foregoing items could have adverse effects on the liquidity of our shares of Common Stock.

In addition, the SEC has recently disclosed that it has developed internal guidelines concerning the use of a resale registration statement to register the securities issued to certain investors in private investment in public equity (PIPE) transactions, where the issuer has a market capitalization of less than $75 million and, in general, does not qualify to file a Registration Statement on Form S-3 to register its securities. The SEC has taken the position that these smaller issuers may not be able to rely on Rule 415 under the Securities Act, which generally permits the offer and sale of securities on a continued or delayed basis over a period of time, but instead would require that the issuer offer and sell such securities in a direct or "primary" public offering, at a fixed price, if the facts and circumstances are such that the SEC believes the investors seeking to have their shares registered are underwriters and/or affiliates of the issuer. It appears that the SEC in most cases will permit a registration for resale of up to one third of the total number of shares of common stock then currently owned by persons who are not affiliates of such issuer and, in some cases, a larger percentage depending on the facts and circumstances. Staff members also have indicated that an issuer in most cases will have to wait until the later of six months after effectiveness of the first registration or such time as substantially all securities registered in the first registration are sold before filing a subsequent registration on behalf of the same investors. The SEC may require as a condition to the declaration of effectiveness of a resale registration statement that we reduce or "cut back" the number of shares of Common Stock to be registered in such registration statement. The result of the foregoing is that a stockholder's liquidity in our Common Stock may be adversely affected in the event the SEC requires a cut back of the securities as a condition to allow the Company to rely on Rule 415 with respect to a resale registration statement, or, if the SEC requires us to file a primary registration statement.

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 4021 N. 75th Street, Suite 201, Scottsdale, Arizona 85251, where we have leased approximately 1,800 square feet of office space through September 30, 2007. Our rent expense is $2,380 per month. 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 2006.

PART II

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

Our common stock is approved for quotation on the NASD 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.

	2007	
	High	**Low**
1st Quarter	$ 0.17	$ 0.12
2nd Quarter (through April 5, 2007)	0.14	0.12

	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

	2005	
	High	**Low**
1st Quarter	$ 1.00	$ 0.33
2nd Quarter	0.52	0.26
3rd Quarter	0.48	0.28
4th Quarter	0.52	0.19

On April 5, 2007, the closing price of our common stock as reported by the OTC Bulletin Board was $0.13 per share. There were approximately 1,200 shareholders of record and beneficial stockholders of our common stock as of April 5, 2007. 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

During the three months ended December 31, 2006, we issued warrants to purchase 43,500 shares of common stock at prices ranging from $0.20 to $1.00 per share. Pursuant to the terms of their respective agreement with us, these warrants were granted to current members of the Bioterrorism Advisory Board and Scientific Advisory Board for participation during the quarter ended December 31, 2006. The warrants will bear a restrictive legend regarding the sale or transfer of such or the underlying securities. The warrants 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. There were less than 35 investors and each investor had such knowledge and experience in financial and business matters that the investor was capable of evaluating the merits and risks of investing in the warrants. No general solicitation or advertising was undertaken in connection with the offer and sale of these shares. Each investor was also provided with access to our Exchange Act reports including our annual report on Form 10-KSB and our quarterly reports on Form 10-QSB.

In December 2006, we completed a private placement, whereby we sold an aggregate of $5,482,600 worth of units to accredited investors. Each unit was sold for $25,000 and consisted of (a) a number of shares of our common stock determined by dividing the unit price by $0.16, and (b) a five-year warrant to purchase a number of shares of our common stock equal to 50% of the number of shares included within the unit, at $0.50 per share. We issued in the private placement an aggregate of 34,266,250 shares of our common stock and warrants to purchase 17,133,125 shares of our common stock. In consideration of the investment, we granted to each investor certain registration rights and anti-dilution rights. We agreed that not before 180 days after the closing of the private placement and not later than 190 days thereafter, that we will file with the SEC a registration statement to register these shares along with the shares underlying these warrants. In the event that we fail to comply with the filing deadline, there shall be a 1% penalty for each 30 day period (or pro rata portion thereof) paid to each investor in cash or additional shares. This penalty amounts to an aggregate of 342,662 shares and 171,331 warrants per 30 day period until a registration statement that includes these shares and warrants is filed or 12 months. As of December 31, 2006, we are not subject to any penalty. As placement agent for the private placement, Joseph Stevens & Co., Inc. and its designees received 5,482,600 shares of our common upon the closing of the private placement. The shares and warrants issued in the private placement and to the placement agent were offered and sold to investors in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

During the three months ended September 30, 2006, we issued warrants to purchase 46,000 shares of common stock at prices ranging from $0.20 to $1.00 per share. Pursuant to the terms of their respective agreement with us, these warrants were granted to current members of the Bioterrorism Advisory Board and Scientific Advisory Board for participation during the quarter ended September 30, 2006. The warrants will bear a restrictive legend regarding the sale or transfer of such or the underlying securities. The warrants 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. There were less than 35 investors and each investor had such knowledge and experience in financial and business matters that the investor was capable of evaluating the merits and risks of investing in the warrants. No general solicitation or advertising was undertaken in connection with the offer and sale of these shares. Each investor was also provided with access to our Exchange Act reports including our annual report on Form 10-KSB and our quarterly reports on Form 10-QSB. 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 August 2006, pursuant to an agreement with the investors in the private placement of October 2004, we issued 4,150,800 shares of common stock and warrants to purchase an additional 1,634,400 shares as penalty for late registration of shares and warrants issued in the placement. The agreement limited the number of shares and warrants which the Company was 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. 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 July 14, 2006, we issued to our Chief Executive Officer, Michael K. Wilhelm, 300,000 common stock purchase warrants for collateralization of promissory notes in 2004. These warrants have an exercise price of $0.25 and expire five years from the date of issuance. 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 July 14, 2006, pursuant to the term of his employment agreement we issued to our Chief Financial Officer, John N. Fermanis, 62,500 common stock purchase warrants. The warrants have an exercise price of $0.158 and expire five years from the date of issuance. 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.

During the three months ended June 30, 2006, we issued warrants to purchase 84,653 shares of common stock at prices ranging from $0.20 to $1.00 per share. Pursuant to the terms of their respective agreement with us, these warrants were granted to current members of the Bioterrorism Advisory Board and Scientific Advisory Board for participation during the quarter ended June 30, 2006. The warrants will bear a restrictive legend regarding the sale or transfer of such or the underlying securities. The warrants 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. There were less than 35 investors and each investor had such knowledge and experience in financial and business matters that the investor was capable of evaluating the merits and risks of investing in the warrants. No general solicitation or advertising was undertaken in connection with the offer and sale of these shares. Each investor was also provided with access to our Exchange Act reports including our annual report on Form 10-KSB and our quarterly reports on Form 10-QSB.

In June 2006, the Company issued 5,000 shares of common stock at $0.09 per share for the exercise of warrants by an investor. 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 June 2006, the Company issued a note payable in the amount of $9,750 in exchange for consulting services. This note bears interest at the rate of 7% per annum. In addition to the note payable, the consulting agreement calls for the issuance of 695,000 common stock purchase warrants if certain milestones are met. The warrants expire five years from the date of issuance and have an exercise price of $0.32. The securities were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On December 12, 2003, the Company entered into a $20,000 promissory note bearing 8% interest per year to an individual accredited investor. On October 15, 2004 in accordance with the terms of the promissory note, accrued interest of $1,354 was converted into 13,454 shares of our common stock releasing the Company from any further obligation under the note. From the date of the note's conversion, these shares were accrued for by the Company and the certificate representing the shares was issued in May 2006. No general solicitation or advertising was undertaken in connection with the offer and sale of the Note. The investor represented to the Company that the investor was purchasing the Note for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the Note and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

During the three months ended March 31, 2006, we issued warrants to purchase 61,500 shares of common stock at prices ranging from $0.125 to $1.00 per share. Pursuant to the terms of their respective agreement with us, these warrants were granted to current members of the Bioterrorism Advisory Board and Scientific Advisory Board for participation during the quarter ended March 31, 2006. The warrants will bear a restrictive legend regarding the sale or transfer of such or the underlying securities. The warrants 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. There were less than 35 investors and each investor had such knowledge and experience in financial and business matters that the investor was capable of evaluating the merits and risks of investing in the warrants. No general solicitation or advertising was undertaken in connection with the offer and sale of these shares. Each investor was also provided with access to our Exchange Act reports including our annual report on Form 10-KSB and our quarterly reports on Form 10-QSB.

In March 2006, we issued 67,616 shares of our common stock for the conversion of principal and accrued interest of an outstanding note payable. 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.

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.

35

ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

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.

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.

COMPANY HISTORY

We were originally incorporated in the State of Delaware in June 1985 under the name Vocaltech, Inc. to develop, design, manufacture and market products utilizing proprietary speech-generated tactile feedback devices. We completed our initial public offering of our securities in October 1987. In January 1992, we effected a 1-for-6.3 reverse stock split of our common stock. We changed our name to InnoTek, Inc. in November 1992. In December 1994, we acquired all of the outstanding stock of InnoVisions, Inc., a developer and marketer of skin protective products, discontinued our prior operations in their entirety and changed our name to DermaRx Corporation. In April 2000, we effected a reverse merger with a subsidiary of Go Public Network, Inc., which was engaged in assisting early-stage development and emerging growth companies with financial and business development services. We changed our name to GoPublicNow.com, Inc., effected a 1-for-5 reverse stock split and discontinued our prior operations in their entirety. In November 2000, we changed our name to GPN Network, Inc. In July 2001, we discontinued the operations of GPN Network, Inc. in their entirety and began looking for appropriate merger partners. Our objective became the acquisition of an operating company with the potential for growth in exchange for our securities. In July 2003, we effected a reverse merger with ImmuneRegen BioSciences, Inc., adopted our current business model and thereafter changed our name to IR BioSciences Holdings, Inc. In July 2003, we effected a

1-for-20 reverse stock split, and in April 2004, we effected a 2-for-1 stock split. In June 2006, our 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

In December 2006, we completed a private placement, whereby we sold an aggregate of $5,482,600 worth of units to accredited investors. Each unit was sold for $25,000 and consisted of (a) a number of shares of our common stock determined by dividing the unit price by $0.16, and (b) a five-year warrant to purchase a number of shares of our common stock equal to 50% of the number of shares included within the unit, at $0.50 per share. We issued in the private placement an aggregate of 34,266,250 shares of our common stock and warrants to purchase 17,133,125 shares of our common stock. In consideration of the investment, we granted to each investor certain registration rights and anti-dilution rights. We agreed that not before 180 days after the closing of the private placement and not later than 190 days thereafter, that we will file with the SEC a registration statement to register these shares along with the shares underlying these warrants. In the event that we fail to comply with the filing deadline, there shall be a 1% penalty for each 30 day period (or pro rata portion thereof) paid to each investor in cash or additional shares. This penalty amounts to an aggregate of 342,662 shares and 171,331 warrants per 30 day period until a registration statement that includes these shares and warrants is filed or 12 months. As of December 31, 2006, we are not subject to any penalty. As placement agent for the private placement, Joseph Stevens & Co., Inc. and its designees received 5,482,600 shares of our common upon the closing of the private placement.

On October 23, 2006, we, through our wholly-owned subsidiary ImmuneRegen BioSciences, Inc., entered into an employment agreement with Hal Siegel, Ph.D. making him the Senior Director of Product Development and Regulatory Affairs of the Company. Dr. Siegel, who is also a member of our Board of Directors, also entered into a change of control agreement on October 23, 2006. Pursuant to terms of the employment agreement, Dr. Siegel will be compensated at an annual base salary of $200,000 for the first year and $210,000 for the second year. Dr. Siegel will also be eligible for discretionary bonuses under the Company's stock option plan during his employment. In addition, Dr. 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.

On September 13, 2006, our Board of Directors granted a one-time discretionary incentive option to purchase 3,500,000 shares of common stock to our President and Chief Executive Officer, Michael K. Wilhelm, per his employment agreement. The grant consisted of 454,545 statutory options and 3,045,455 non-statutory options. The options have a per share exercise price of $0.22, which is 110% of the closing price on the date of the grant, and a term of five years.

In August 2006, pursuant to an agreement with the investors in the private placement of October 2004, we issued 4,150,800 shares of common stock and warrants to purchase an additional 1,634,400 shares as penalty for late registration of shares and warrants issued in the placement. The agreement limited the number of shares and warrants which the Company was 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.

On August 1, 2006, the Company converted two cash advances into unsecured senior promissory notes, in the respective amounts of $50,000 and $20,000, with individual accredited investors, one of whom was a Director. Following the payment of fees and expenses, the Company received net proceeds of approximately $68,600.

In July 2006, the Company received a cash advance from a Director in the amount of $25,000 to be used as an upfront payment for a radiation study. This advance bears interest at the rate of 12% per annum. This cash advance was not used, as no upfront payment was required, and subsequently, principal and interest was returned on August 30, 2006.

On July 25, 2006, we entered into an unsecured senior promissory note in the amount of $250,000 with an accredited investor. Following the payment of commissions and expenses, the Company received net proceeds of approximately $210,000. The note was repaid in October 2006.

On July 14, 2006, our Board of Directors granted a one-time discretionary incentive stock option to purchase 1,896,970 shares of common stock to our President and Chief Executive Officer, Michael K. Wilhelm, per his employment agreement. The options have a per share exercise price of $0.231, which is 110% of the closing price on the date of the grant, and a term of five years. The options were granted in furtherance of a resolution by our Board on August 8, 2005 pursuant to which the options were to be granted at such time that the Company's 2003 Stock Plan is amended to authorize additional shares, which was effected by approval of our shareholders on June 28, 2006.

On July 14, 2006, we issued to our Chief Executive Officer, Michael K. Wilhelm, 300,000 common stock purchase warrants for collateralization of promissory notes in 2004. These warrants have an exercise price of $0.25 and expire five years from the date of issuance.

On July 14, 2006, pursuant to the term of his employment agreement we issued to our Chief Financial Officer, John N. Fermanis, 62,500 common stock purchase warrants. The warrants have an exercise price of $0.158 and expire five years from the date of issuance.

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

In June 2006, we issued 5,000 shares of common stock pursuant to the exercise of a warrant at a price of $0.09 per share.

In June 2006, the Company issued a note payable in the amount of $9,750 in exchange for consulting services. This note bears interest at the rate of 7% per annum. In addition to the note payable, the consulting agreement calls for the issuance of 695,000 common stock purchase warrants if certain milestones are met. The warrants expire five years from the date of issuance and have an exercise price of $0.32.

On June 28, 2006, our shareholders voted to (i) approve an amendment to our Certificate of Incorporation, as amended, to increase the number of authorized shares of Common Stock from 100,000,000 to 250,000,000 and (ii) approve an amendment to our 2003 Stock Option, Deferred Stock and Restricted Stock Plan to increase the number of shares of our Common Stock reserved and available for issuance under the Plan from 3,600,000 to 20,000,000.

In May 2006, we issued 34,464 shares of S-8 common stock to a consultant for services provided for business development.

In May 2006, we issued 19,288 shares of common stock to an investor for the conversion of accrued interest at $0.125 per share.

In May 2006, we issued 16,324 shares of common stock to an investor for the conversion of accrued interest at $0.125 per share.

In May 2006, we issued 13,454 shares of common stock at to an investor for the conversion of accrued interest at $0.125 per share.

On April 13, 2006, we entered into an unsecured Senior Promissory Note in the amount of $500,000. Following the payment of commissions and expenses, we received net proceeds of approximately $439,875

In March 2006, per his employment agreement we issued 100,000 shares of our common stock to our Chief Financial Officer, John Fermanis.

In March 2006, we issued 67,616 shares of our common stock for the conversion of principal and accrued interest of an outstanding note payable.

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™. We defined Radilex and Viprovex as derivatives of Homspera due to the potential difference in formulations and indications for use of such compounds. Our goal is to develop these potential drug candidates to be used as possible countermeasures for homeland security threats, including radiological, chemical and biological agents, such as influenza and anthrax. We hope there may exist not only a market for products related to biodefense through governmental purchasing, but there also may exist a potential commercial market for treatments of cancer treatment side-effects and seasonal influenza.

Our patents, patent applications and continued research are 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, these 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 early, 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 the results of our studies 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 on the development of two potential formulations derived from Homspera, Radilex and Viprovex.

We are researching Radilex for use as a potential treatment for acute exposure to radiation. To we have sponsored seven studies and co-sponsored three studies all of which were conducted utilizing rodents. The results of these studies suggest Radilex may play a role in increased survival among tested rodents following exposure to lethal doses of gamma 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. Based on early studies on Homspera and existing literature on Substance P, we are researching the efficacy of 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. To date we have sponsored three studies related to the treatment of influenza, three on the exposure to anthrax spores and one on exposure to formalin. We believe the results of these studies indicated potential efficacy in the use of Viprovex as both a stand alone treatment and an adjuvant, to be used in conjunction with other drugs. 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. 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.
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 filed patent applications and provisional patent applications for the use of Sar^9, Met $(O_2)^{11}$-Substance P, the active ingredient in Homspera, Radilex and Viprovex. The intellectual property owned by us is for various potential uses of Sar^9, Met $(O_2)^{11}$-Substance P. We own two issued U.S. and two issued foreign patents. We also have 35 pending patents relating to the use of Sar^9, Met $(O_2)^{11}$-Substance P, comprised of four pending Patent Cooperation Treaty (PCT) applications, nine pending U.S. provisional patent applications and 22 pending foreign provisional patent applications.

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

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. 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.

Our principal offices are located at 4021 North 75th Street, Suite 201, Scottsdale, Arizona 85251 and our telephone number is (480) 922-3926. We are incorporated in State of Delaware. We maintain a website at www.immuneregen.com. The reference to our worldwide web address does not constitute incorporation by reference of the information contained on our website.

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 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 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, 2005 and 2006 was limited. We spent approximately $484,029 and $237,005 in 2006 and 2005, respectively, in research and development activities related to the development of Radilex and Viprovex. From our inception in October 2002, we have spent $1,026,597 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 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 $700,000 in an effort to further develop Radilex and Viprovex. This research and development cost estimate includes additional animal pharmacology studies, formulation and animal safety/toxicity studies. If we receive additional funds, through either investment funding or grants, we expect we will increase our research and development spending.

We believe we will be able to apply to the FDA for approval for the use of Radilex for the treatment of acute radiation syndrome and for approval for the use of Viprovex for the treatment of maladies caused by exposure to biological and chemical agents based upon the "animal efficacy rule." Therefore, we intend to 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. Through development under this rule, we believe that we could potentially incur less development costs as compared to the more traditional drug development model, as Phase III of the FDA required drug approval process is not required under the animal efficacy rule; however, there can be no assurances that we will be able to benefit from less development costs or that we will ever qualify for approval under the “animal efficacy rule”. 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.

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 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.

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 24 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 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, 2006, 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.

Research and Development of Radilex in Radiological Exposure Applications

To date we have sponsored seven radiation studies and co-sponsored three radiation studies all of which were conducted utilizing rodents to study dose response to radiation, the impact on survival and to distinguish survival response using different forms of drug delivery. In each of these studies mice were exposed to varying levels of radiation.

In these studies we have collected data that we believe suggests that Radilex shows efficacy in treating ARS by combating neutropenia and thrombocytopenia, which is the decrease in populations of blood levels of white blood cells and platelets and the major medical conditions associated with acute exposure to radiation. Loss of these cells results in increased sensitivity to infection and to uncontrolled bleeding, both of which can be potentially life-threatening. Further, as treatment for cancer often includes radiation treatment, we believe that the potential also exists for Radilex to be used for cancer patients as a stand alone treatment or a co-therapeutic agent to be used with other drugs as treatment.

Acute total body irradiation exposure studies have been performed at the University of Arizona Cancer Center and at Oak Ridge National Laboratories (ORNL). We believe that data collected in studies performed at the Oak Ridge National Laboratory in 2006 revealed that Radilex not only prolonged survival of animals exposed to lethal gamma irradiation, but also appeared to reverse the loss of white blood cells that comprise the immune system, as well as platelets necessary to control blood clotting, subsequently leading to an increase in survival rates.

Further, we believe that our survival data from irradiated mice studies and mechanistic studies in cell culture have shown indications of hematopoietic stem cell replenishment of circulating leukocytes and platelets, which could be of value in radiation-treated cancer patients.

Continuing radiation studies are expected to be performed at both the Translational Genomics Research Institute (TGen) and TGen Drug Development Services (TD2, its drug development arm) , Pacific Northwest National Laboratory, and Stem Cells Technology Inc. to further explore the impact of radiation on the hematopoietic system of Radilex-exposed animals. In addition, future studies will be designed to examine mechanistic indicators at both high levels of radiation where Radilex has shown protection, as well as at lower levels. If successful, these studies would demonstrate the ability of Radilex to address both the government market, as a countermeasure to radiological dispersion devices, such as dirty bombs, as well as the cancer market, as an adjuvant treatment candidate potentially ameliorating the side effects resulting from cancer radiotherapy

We are also in discussions with LAB Research Inc. to conduct an efficacy study in a whole body gamma irradiation model in rhesus monkeys utilizing Radilex. To date, we have discussed protocols and received a price quotation from LAB Research.

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.

Research and Development of Viprovex in Biological Exposure Applications

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 believe that results from our animal 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.
Influenza

In October 2003 the AFOSR 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. Subsequently, we have sponsored three influenza studies at Virion Laboratories, one of which is still ongoing, utilizing rodents to test the efficacy of Viprovex in treating the avian influenza A/Wuhan/359/95 (H3N2), a model system for studying the H5N1 avian influenza.

We believe that the data acquired to date in examining the effect of Viprovex on influenza infection suggests an anti-viral action occurs in the lungs and, more noticeably, in the nose. In conjunction with this suggested anti-viral effect, we believe Viprovex may play a role in the normalization of animal weight and temperature. Further, we believe we witnessed differences in peptides signaling molecules released by cells of the immune system to mediate inflammation and immune responses. We believe that such Viprovex-induced changes in immune response 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 other pharmacological agents, Viprovex might be an effective adjuvant therapeutic on treating or preventing influenza.

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

Anthrax

To date we have sponsored three anthrax studies all of which were conducted utilizing rodents to determine if Viprovex will reduce the mortality rate of an active infection of pulmonary anthrax. In our opinion, when treated with Viprovex prior to exposure to anthrax spores, Viprovex elicited protective, prophylactic efficacy and when treated a short time period after exposure to anthrax spores, Viprovex elicited therapeutic efficacy.

In 2006 we completed a series of studies with Hyperion Biotechnology Inc. at their laboratory facilities located at Brooks City-Base in San Antonio, Texas. The purpose of these studies was to determine if Viprovex could reduce the mortality rate of an active infection of pulmonary anthrax. The first of these studies was initiated in October 2005. This research suggested, we believe, that Viprovex offers protection from anthrax exposure in a mouse model. In these studies, we witnessed mice treated with Viprovex to have a greater survival rate 11 days post-exposure to anthrax spores. Additionally, we believe that this research suggests Viprovex to elicit a dose-dependent prophylactic protection from anthrax in a mouse model.

Further research, we believe supports these findings of prophylactic efficacy of Viprovex against anthrax and also suggests Viprovex to show efficacy in increasing survival rates in mice pretreated with anthrax. Additionally, preliminary results, we believe suggest that Viprovex, when used as an adjuvant, 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

In March 2007, we began the first of a series of studies to investigate the therapeutic effects of Viprovex on acute melioidosis. These studies are to be performed in conjunction with Singapore's Defense Medical & Environmental Research Institute, DSO National Laboratories ("DSO"). The studies are to be funded by DSO and are expected to be completed during the third quarter of 2007.

Research and Development of Viprovex in Chemical Exposure Applications

Based on early studies on Homspera and existing literature on Substance P, we are researching the efficacy of Viprovex as a potential treatment for exposure to chemical agents, such as formalin. Formalin is a solution of formaldehyde gas dissolved in water, used industrially and toxic typically via crosslinking of proteins to other nearby proteins. 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.

We believe our early AFOSR rodent studies suggests the administration of Substance P and Homspera to animals exposed to JP-8 decreased the immune system effects, while administration of Substance P antagonists compounded the deleterious effects. Further experiments performed using Viprovex examined effectiveness in preventing lung injury on inhalation of toxic fumes. We believe data collected from these studies suggest Viprovex to exhibit anti-inflammatory effects in animal models.

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

Research and Development as an Adjuvant Therapeutic

Adjuvants are unique among active ingredients in drugs in that they are designed to not stimulate an immune response against themselves, but they are required to augment the immune response against other, co-administered compounds.

Data collected from studies, we believe, suggest that Homspera may have potential value as a co-therapeutic agent or vaccine adjuvant. Studies performed in animal models of influenza and acute radiation syndrome have revealed the potential capability of Homspera to enhance the action of approved anti-viral medications as well as to provide adjunctive impact on anti-tumor radiation therapy.

We believe that, in conjunction with other influenza therapeutics, Homspera might be an effective adjuvant therapeutic by decreasing the number of viruses at which the viral neuraminidase-targeted therapeutic must act. Additionally, while these results are preliminary, we believe that data suggests Homspera, when used as an adjuvant, could play an important role, in conjunction with other therapies, in improving treatments of anthrax exposure. Further, we believe that data also suggests a potential for Homspera to be used as a co-therapy for cancer patients, as secondary treatment often involves radiation treatments following chemotherapy, in an attempt to kill more of the cancer cells.

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

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 Radilex as a possible therapeutic for radiation exposure. Any of these occurrences would have a material negative impact on our business and our liquidity as it may cause us to seek additional capital sooner than expected and allow our competitors to successfully enter the market ahead of us.

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

OFF-BALANCE SHEET ARRANGEMENTS

There were no off-balance sheet arrangements made in 2006.

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, 2006, we have incurred losses of $13,285,180. 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, 2006, Sales, General and Administrative expenses (“SG&A”) were $2,445,317, a decrease of $89,100 or approximately 4% compared to SG&A expenses of $2,534,417 during the 12 months ended December 31, 2005. The decrease was primarily due to lower costs for non-cash compensation.

For the twelve months ending December 31, 2006, Interest Expense (net) was $48,508 , an increase of approximately 526% compared to Interest Income (net) of $11,386 during the 12 months ended December 31, 2005. Interest Expense increased because the Company entered into notes payable during the twelve months ended December 31, 2006. We expect Interest Expense to decrease during the coming twelve months as we have paid off outstanding notes payable with the proceeds of the Private Placement.

During the twelve months ending December 31, 2006, we recognized a gain of $438,601 for the cost of the penalty for the late registration of shares which was a decrease of $3,069,362 or approximately 117% compared to the cost of penalty for late registration of shares for the twelve months ended December 31, 2005. The reduction of the expense was due to stopping the accrual of penalty shares in 2006 and the reversal of the accrual for penalty shares and warrants which had been previously accrued in excess of the cap amount agreed to by the shareholders.

NET LOSS

For the reasons stated above, our net loss for the twelve months ending December 31, 2006 was $1,486,046, or $0.02 per share versus a net loss for the twelve months ending December 31, 2005 of $4,591,107 or $0.07 per share. For the period of inception (October 30, 2002) through December 31, 2006, our net loss was $13,285,180, or $0.28 per share.

We expect that losses will continue through the period ending December 31, 2010.

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 $1,486,046 and $2,035,484, respectively, for the year ended December 31, 2006. This loss, in addition to a lack of operational history, raises substantial doubt about our ability to continue as a going concern. We currently have sufficient working capital to fund operations through January 2008. 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 January 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.

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.

The Company 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 the Company, pursuant to Rule 477 of Regulation C of the Securities Act of 1933, as amended, applied for an order granting the immediate withdrawal of its 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 $994,574 during the three months ended June 30, 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 the Company 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, 2006, we had current assets of $2,831,502 consisting of cash of $2,752,103 and prepaid services of $79,399. Also, at December 31, 2006, we had current liabilities of $510,969, consisting of accounts payable and accrued liabilities of $460,969 and notes payable of $50,000. This resulted in working capital of $2,320,533. During the twelve months ended December 31, 2006, we used cash in operating activities of $2,035,484. From the date of inception (October 30, 2002) to December 31, 2006, we had a net loss of $13,285,180 and used cash of $5,993,942 in operating activities. We met our cash requirements from our inception through December 31, 2006 via the private placement of $7,877,901 of our common stock and $908,628 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.

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 have agreed that not before 180 days after the closing of the private placement and not later than 190 days thereafter, that we shall file with the SEC an appropriate registration statement to register these shares along with the shares underlying these warrants. In the event that we fail to comply with the filing deadline, there shall be a 1% penalty for each 30 day period (or pro rata portion thereof) paid to each investor in cash or additional shares. This penalty amounts to an aggregate of 342,662 shares and 171,331 warrants per 30 day period until such a time as a registration statement that includes these shares and warrants is filed or 12 months. As of December 31, 2006, we are not subject to any penalty.

On August 1, 2006, we converted two cash advances into unsecured senior promissory notes bearing interest at the rate of 12% per annum, in the respective amounts of $50,000 and $20,000. These notes were entered into with individual accredited investors, one of whom was a Director. Following the payment of fees and expenses, we received net proceeds of approximately $68,600. On October 6, 2006, principal and interest of $733 was returned on the $20,000 note.

In July 2006, we received a cash advance from a Director in the amount of $25,000 to be used as an upfront payment for a radiation study. This advance bears interest at the rate of 12% per annum. This cash advance was not used, as no upfront payment was required, and subsequently, principal and interest of $370 was returned on August 30, 2006.

On July 25, 2006, we entered into an unsecured senior promissory note bearing interest at the rate of 12% per annum in the amount of $250,000 with an accredited investor. Following the payment of commissions and expenses, the Company received net proceeds of approximately $210,000. On October 6, 2006 principal and interest of $5,583 was returned.

In June 2006, we issued 5,000 shares of common stock for cash of $450 pursuant to the exercise of a warrant at $0.09 per share.

In June 2006, we issued a note payable in the amount of $9,750 in exchange for consulting services. This note bears interest at the rate of 7% per annum. In addition to the note payable, the consulting agreement calls for the issuance of 695,000 common stock purchase warrants if certain milestones are met. The warrants expire five years from the date of issuance and have an exercise price of $0.32. On October 11, 2006, principal and interest of $237 was returned.

On April 13, 2006, we entered into an unsecured senior promissory note bearing interest at the rate of 12% per annum in the amount of $500,000 with an accredited investor. Following the payment of commissions and expenses, we received net proceeds of approximately $439,875 On October 6, 2006 principal and interest of $28,500 was returned.

On July 25, 2006, we entered into an unsecured senior promissory note in the amount of $250,000 with an accredited investor. Following the payment of commissions and expenses, the Company received net proceeds of approximately $210,000.

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 calls for a salary at the rate of $275,000 per annum and provides for 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 will pay 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.

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 2006, 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). Based on our current plan of operations all of our current funding is expected to be depleted by the end of January 2008. If we are not successful in generating sufficient liquidity from operations or in raising sufficient capital resources, it would have a material adverse effect on our business, results of operations, liquidity and financial condition.

While we have raised capital to meet our working capital and financing needs in the past through debt and equity financings, additional financing will be required in order to implement our business plan and to meet our current and projected cash flow deficits from operations and development. There can be no assurance that we will be able to consummate future debt or equity financings in a timely manner on a basis favorable to us, or at all. If we are unable to raise needed funds, we will not be able to develop or enhance our potential products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets 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 January 2008. Thereafter, we believe that we will require an additional $500,000 to meet our expenses over the next 12 months.

Acquisition or Disposition of Plant and Equipment

We acquired $32,397 worth of property, plant or equipment for the year ended December 31, 2006. 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, 2006, we have relied on the services of outside consultants for services and currently have six total employees, one contract employee, four full-time employees and one part-time employee. 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; and, the fourth 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.

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, 2006, and changes during the period ended are presented below:

	Options	Weighted Average Exercise Price
Outstanding at December 31, 2005	317,242	$ 5.30
Issued	5,596,970	$ 0.22
Exercised	--	--
Forfeited or expired	--	--
Outstanding at December 31, 2006	5,914,212	$ 0.50
Non-vested at December 31, 2006	2,023,952	$ 0.22
Exercisable at December 31, 2006	3,890,260	$ 0.64

46

Aggregate intrinsic value of options outstanding and exercisable at December 31, 2006 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 $0.15 as of December 29, 2006, and the exercise price multiplied by the number of options outstanding. As of December 31, 2006, total unrecognized stock-based compensation expense related to stock options was $264,274. During the year ended December 31, 2006 the Company charged $296,394 to operations related to recognized stock-based compensation expense for employee stock options

For purposes of pro forma disclosures, the estimated fair value of the options is amortized over the options' vesting period. The Company's pro forma information was as follows:

	Twelve months ended December 31, 2005
Net loss, as reported	$ (4,591,107)
Compensation recognized under APB 25	--
Compensation recognized under SFAS 123	(83,150)
Pro forma net loss	$ (4,674,257)
Pro forma loss per share	$ (0.07)

Recent Accounting Pronouncements

In February 2006, the FASB issued SFAS No. 155. "*Accounting for certain Hybrid Financial Instruments an amendment of FASB Statements No. 133 and 140,"* or SFAS No. 155. SFAS No. 155 permits fair value remeasurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation, clarifies which interest-only strips and principal-only strips are not subject to the requirements of Statement No. 133, establishes a requirement to evaluate interests in securitized financial assets to identify interests that are freestanding derivatives or that are hybrid financial instruments that contain an embedded derivative requiring bifurcation, clarifies that concentrations of credit risk in the form of subordination are not embedded derivatives, and amends SFAS No. 140 to eliminate the prohibition on a qualifying special purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument. SFAS 155 is effective for all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006. We do not expect the adoption of SFAS 155 to have a material impact on our consolidated financial position, results of operations or cash flows.

In March 2006, the FASB issued FASB Statement No. 156, Accounting for Servicing of Financial Assets - an amendment to FASB Statement No. 140. Statement 156 requires that an entity recognize a servicing asset or servicing liability each time it undertakes an obligation to service a financial asset by entering into a service contract under certain situations. The new standard is effective for fiscal years beginning after September 15, 2006. The adoption of SFAS No.156 did not have a material impact on the Company's financial position and results of operations.

In July 2006, the FASB issued Interpretation No. 48 (FIN 48). "*Accounting for uncertainty in Income Taxes"*. FIN 48 clarifies the accounting for Income Taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition and clearly scopes income taxes out of SFAS 5, "*Accounting for Contingencies"*. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company does not expect adoption of this standard will have a material impact on its financial position, operations or cash flows.

In September 2006 the Financial Account Standards Board (the "FASB") issued its Statement of Financial Accounting Standards 157, Fair Value Measurements. This Statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles (GAAP), and expands disclosures about fair value measurements. This Statement applies under other accounting pronouncements that require or permit fair value measurements, the Board having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, this Statement does not require any new fair value measurements. However, for some entities, the application of this Statement will change current practice. FAS 157 effective date is for fiscal years beginning after November 15, 2007. The Company does not expect adoption of this standard will have a material impact on its financial position, operations or cash flows.

In September 2006 the FASB issued its Statement of Financial Accounting Standards 158 "Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans". This Statement improves financial reporting by requiring an employer to recognize the overfunded or underfunded status of a defined benefit postretirement plan (other than a multiemployer plan) as an asset or liability in its statement of financial position and to recognize changes in that funded status in the year in which the changes occur through comprehensive income of a business entity or changes in unrestricted net assets of a not-for-profit organization. This Statement also improves financial reporting by requiring an employer to measure the funded status of a plan as of the date of its year-end statement of financial position, with limited exceptions. The effective date for an employer with publicly traded equity securities is as of the end of the fiscal year ending after December 15, 2006. The Company does not expect adoption of this standard will have a material impact on its financial position, operations or cash flows

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.

ITEM 7. FINANCIAL STATEMENTS

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FINANCIAL STATEMENTS AND SCHEDULES
DECEMBER 31, 2006 AND 2005

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

IR BIOSCIENCES HOLDINGS, INC.

IR BioSciences Holdings, Inc.
Index to Financial Statements

RUSSELL BEDFORD STEFANOU MIRCHANDANI LLP
CERTIFIED PUBLIC ACCOUNTANTS

REPORT OF INDEPENDENT REGISTERED CERTIFIED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheet of IR BioSciences Holdings, Inc. a development stage company as of December 31, 2006 and the related consolidated statements of losses, statement of stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2006 and the period October 22, 2002 (date of inception) through December 31, 2006. These financial statements are the responsibility of the company's management. Our responsibility is to express an opinion on the financial statements based upon our audits.

We have conducted our audits in accordance with auditing standards of the Public Company Accounting Oversight Board (PCAOB) (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 our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of IR BioSciences Holdings, Inc. a development stage company at December 31, 2006 and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2006 and the period October 22, 2002 (date of inception) through December 31, 2006 in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note A to the consolidated financial statements, the Company adopted the provisions of Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment", effective January 1, 2006.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in the Note A to the accompanying financial statements, the Company is in the development stage and has not established a source of revenues. This raises substantial doubt about the company’s ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ RUSSELL BEDFORD STEFANOU MIRCHANDANI LLP
Russell Bedford Stefanou Mirchandani LLP

New York, New York
March 23, 2007

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

Assets		
Current assets		
Cash and cash equivalents	$	2,752,103
Prepaid services and other current assets		77,899
Salary advance		1,500
Total current assets		2,831,502
Deposits and other assets		2,260
Furniture and equipment, net of accumulated depreciation of $12,242 (Note B)		28,242
Total assets	$	2,862,004
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities (Note C)		460,969
Current portion of Notes Payable (Note F)		50,000
Total current liabilities		510,969
Commitments and Contingencies (Note I)		-
Stockholders' 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;		
108,041,897 shares issued and outstanding at December 31, 2006 (Note G)		108,042
Additional paid-in capital (Notes G, H)		15,522,690
Common stock subscribed		5,483
Deficit accumulated during the development stage		(13,285,180)
Total stockholder's equity		2,351,035
Total liabilities and stockholders' equity	$	2,862,004

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

IR BioSciences Holdings, Inc. and Subsidiary
(A Development Stage Company)
Consolidated Statements of Losses
For the years ended December 31, 2006 and 2005,
And for the period of inception
(October 30, 2002) to December 31, 2006

	For the Year Ended December 31,		For the Period October 30, 2002 to December 31, 2006
	2006	2005	
Revenues	$ -	$ -	$ -
Operating expenses:			
Selling, general and administrative expenses	$ 2,445,317	$ 2,534,417	$ 10,569,618
Merger fees and costs	-	-	350,000
Financing cost	-	-	90,000
Impairment of intangible asset costs	-	6,393	6,393
Total operating expenses	2,445,317	2,540,810	11,016,011
Operating loss	(2,445,317)	(2,540,810)	(11,016,011)
Other expense:			
Cost of penalty for late registration of shares	(438,601)	2,630,761	2,192,160
(Gain) loss from marking to market - warrant portion of penalty for late registration of shares	(123,505)	(254,693)	(378,198)
(Gain) loss from marketing to market - stock portion of penalty for late registration of shares	(445,673)	(314,385)	(760,058)
Interest (income) expense, net	48,508	(11,386)	1,215,265
Total other (income) expense	(959,271)	2,050,297	2,269,169
Income (loss) before income taxes	(1,486,046)	(4,591,107)	(13,285,180)
Provision for income taxes	-	-	-
Net (loss)	$ (1,486,046)	$ (4,591,107)	(13,285,180)
Net income (loss) per share - basic and diluted	$ (0.02)	$ (0.07)	$ (0.28)
Weighted average shares outstanding - basic and diluted	73,234,541	67,691,598	47,154,801

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

IR Biosciences Holding, Inc. and Subsidiary
(A Development Stage Company)
Consolidated Statement of Stockholders' Equity (Deficit)
From date of inception (October 30, 2002) to December 31, 2006

	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)	-	-	-
	185,578	186	30,815		-	-	31,001

Sale of common stock for cash at $0.1671 per share in December 2002							
Net loss for the period from inception (October 30, 2002) to December 31, 2002	-	-	-	-	-	(45,918)	(45,918)
Balance at December 31, 2002 (reflective of stock splits)	18,257,042	18,257	31,776	(9,000)	-	(45,918)	(4,885)
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
	2,368,130	2,368	(123,168)	-	-	-	(120,799)

Costs of GPN Merger in July 2003							
Value of warrants issued with extended notes payable in October 2003	-	-	189,937	-	-	-	189,937
-							
Value of Company warrants issued in conjunction with	-	-					
fourth quarter notes payable issued October through December 2003			207,457	-	-	-	207,457
		-					
Value of warrants contributed by founders in conjunction with							
fourth quarter notes payable issued October through December 2003	-	-	183,543	-	-	-	183,543
Value of warrants issued for services in October through December 2003	-	-	85,861	-	-	-	85,861
Net loss for the twelve	-	-	-	-	-	(1,856,702)	(1,856,702)

month period ended December 31, 2003							
-							
Balance at December 31, 2003	23,431,300	23,431	1,035,441	-	-	(1,902,620)	(843,748)
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)	-	-	-
Shars 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)	-	-	-
	8,000	8	1,192	-	-	-	1,200

Shares sold for cash at $0.15 per share in March, 2004							
Shares issued at $0.50 per share to consultants for services rendered in March 2004	20,000	20	9,980	-	-	-	10,000
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)	-	-	-
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 2004	500,000	500	499,500	(500,000)	-	-	-
Beneficial Conversion Feature associated with notes	-	-					

payable issued in June 2004			3,000	-	-	-	3,000
Issuance of warrants to note holders in April, May, and June 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)	-	-	-
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 costs	-	-	607,922	-	-	-	607,922
Issuance of warrant to officer in October, 2004	-	-	112,697	-	-	-	112,697
Issuance of stock to investment bankers in	4,900,000	4,900	(4,900)	-	-	-	-

October 2004 for commissions earned							
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 common stock at $0.075 to $0.125 per share	6,703,151	6,703	417,514	-	-	-	424,217
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
	(9,002)	(9)	9	-	-	-	-

Shares issued in error to be cancelled							
Amortization of deferred compensation through December 31, 2004	-	-	-	2,729,454	-	-	2,729,454
Loss for the twelve months ended December 31, 2004	-	-	-	-	-	(5,305,407)	(5,305,407)
Balance at December 31, 2004	62,423,388	62,423	7,922,943	(169,986)	-	(7,208,027)	607,353
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
Value of warrants issued to investors and service providers in June 2005	-	-	32,991	-	-	-	32,991
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
	-	-	-	199,726	-	-	199,726

Amortization of deferred comp for the twelve months ended December, 2005							
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	69,436,319	69,435	9,465,501	(2,760)	-	(11,799,134)	(2,266,958)
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	34,464	35	16,162	-	-	-	16,197

in May 2006 to a consultant for services provided							
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 per share in May, 2006	16,324	16	2,025	-	-	-	2,041
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	-	-	3,495	-	-	-	3,495

committee in September 2006							
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
	-	-	185,472	-	-	-	185,472

Value of options issued to officer							
Balance at December 31, 2006	-	-	-	-	-	(1,486,046)	(1,486,046)
	$ 108,041,897	$ 108,042	$ 15,522,690	$ -	$ 5,483	$ (13,285,180)	$ 2,351,035

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

IR BioSciences Holdings, Inc. and Subsidiary
(A Development Stage Company)
Consolidated Statements of Cash Flows For the year ended December 31, 2006 and 2005, and for the period of inception (October 30, 2002) to December 31, 2006

	For the Year Ended December 31,		For the Period October 30, 2002 to
	2006	**2005**	**December 31, 2006**
Cash flows from operating activities:			
Net loss	$ (1,486,046)	$ (4,591,107)	$ (13,285,180)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash compensation	398,663	520,853	4,319,516
Cost of penalty for late registration of shares - stock portion	(360,197)	1,991,923	1,631,726
Cost of penalty for late registration of shares - warrant portion	(78,404)	638,838	560,434
(Gain) loss from marking to market - stock portion of penalty for late registration of shares	(445,673)	(314,385)	(760,058)
(Gain) loss from marking to market - warrant portion of penalty for late registration of shares	(123,505)	(254,693)	(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	6,393
Interest expense	-	4,007	156,407
Amortization of discount on notes payable	-	-	1,006,935
Depreciation and amortization	8,381	3,201	37,599
Changes in operating assets and liabilities:			
Prepaid services and other assets	(38,392)	9,946	(35,158)
Accounts payable and accrued expenses	6,064	100,911	662,017
Salary advance	(1,500)	-	(1,500)
Net cash used in operating activities	(2,035,484)	(1,884,113)	(5,993,942)
Cash flows from investing activities:			
Acquisition of property and equipment	(32,397)	-	(40,484)
Net cash used in investing activities	(32,397)	-	(40,484)
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	(779,750)	(14,997)	(1,044,747)
Shares of stock sold for cash	4,613,549	1,190,856	7,873,451

Proceeds from exercise of warrant	450	4,000	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	4,554,124	1,179,859	8,786,529
Net increase (decrease) in cash and cash equivalents	2,486,243	(704,254)	2,752,103
Cash and cash equivalents at beginning of period	265,860	970,114	-
Cash and cash equivalents at end of period	$ 2,752,103	$ 265,860	$ 2,752,103
Supplemental disclosures of cash flow information:			
Cash paid during the period for:			
Interest	$ 36,500	$ 1,706	$ 80,053
Taxes	$ -	$ -	$ -
Acquisition and capital restructure:			
Assets acquired	-	-	-
Liabilities assumed	-	-	(120,799)
Common stock retained	-	-	(2,369)
Adjustment to additional paid-in capital	-	-	123,168
Organization costs	-	-	350,000
Total consideration paid	$ -	$ -	$ 350,000.00
Common stock issued in exchange for proprietary rights	$ -	$ -	$ 9,250
Common stock issued in exchange for services	$ 16,197	$ 10,000	$ 2,941,483
Common stock issued in exchange for previously incurred debt and accrued interest	$ 5,807	$ 65,003	$ 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	$ 347,268	$ 279,949	$ 1,119,649
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	$ 199,726	$ 202,486
Fair value of common stock and warrants in payable in connection with late filing of registration statement	$ 1,053,904	$ 2,630,761	$ 3,684,664
Gain from marking to market - stock portion of penalty for late registration of shares	$ (805,870)	$ 314,385	$ (1,124,255)
Gain from marking to market - warrant portion of penalty for late registration of shares	$ (201,910)	$ 254,693	$ (456,603)
Impairment of intangible asset	$ -	$ 6,393	$ 6,393
Issuance of stock to Officer, previously accrued	$ 41,416	$ -	$ 41,416
Value of warrants issued to members of advisory board	$ 22,688	$ -	$ 22,688
Services for note payable	$ 9,750	$ -	$ 9,750

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

IR BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)
NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2006 AND 2005
AND FOR THE PERIOD FROM OCTOBER 30, 2002
(INCEPTION) TO DECEMBER 31, 2006

NOTE A - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

A summary of the significant accounting policies applied in the preparation of the accompanying consolidated financial statements follows.

Nature of Business

IR BioSciences Holdings, Inc. (the "Company," "we," or "us") formerly GPN Network, Inc. ("GPN") is currently a development stage company under the provisions of Statement of Financial Accounting Standards ("SFAS") No. 7. The Company, which was incorporated under the laws of the State of Delaware on October 30, 2002, is a development-stage biopharmaceutical company. Through our wholly owned subsidiary, ImmuneRegen BioSciences, Inc., we are engaged in the research and development of potential drugs. Our goal is to develop therapeutics to be used for the protection of the body from exposure to harmful agents such as toxic chemicals and radiation, as well as, biological agents, including influenza and anthrax. Our research and development efforts are at a very early stage and Radilex and Viprovex have only undergone pre-clinical testing in mice. From its inception through the date of these financial statements, the Company has recognized no revenues and has incurred significant operating expenses.

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, ImmuneRegen BioSciences, Inc. Significant inter-company transactions have been eliminated in consolidation.

Going Concern

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As shown in the accompanying financial statements during the years ended December 31, 2006 and 2005, the Company incurred losses from operations of $1,486,046 and $ 4,591,107, respectively. This among other factors may indicate that the Company will be unable to continue as a going concern for a reasonable period of time.

In order to address our capital requirements, we intend to seek to raise additional cash for working capital purposes through the public or private sales of debt or equity securities, the procurement of advances on contracts or licenses, funding from joint-venture or strategic partners, debt financing or short-term loans, or a combination of the foregoing. We may also seek to satisfy indebtedness without any cash outlay through the private issuance of debt or equity securities. There can be no assurance the Company will be successful in its effort to secure additional equity financing.

If operations and cash flows continue to improve through these efforts, management believes that the Company can continue to operate. However, no assurance can be given that management's actions will result in profitable operations or the resolution of its liquidity problems.

The accompanying consolidated financial statements do not include any adjustments that might result should the Company be unable to continue as a going concern.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reported periods. Actual results could materially differ from those estimates.

Cash and Cash Equivalents

For purposes of the statement of cash flows, cash equivalents include all highly liquid debt instruments with original maturities of three months or less which are not securing any corporate obligations.

Long-lived Assets

The Company accounts for its long-lived assets under the provision of Statements of Financial Accounting Standards No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets To Be Disposed Of." The Company's long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Events relating to recoverability may include significant unfavorable changes in business conditions, recurring losses, or a forecasted Inability to achieve break-even operating results over an extended period. The Company evaluates the recoverability of long-lived assets based upon forecasted undiscounted cash flows. Should an impairment in value be indicated, the carrying value of intangible assets will be adjusted, based on estimates of future discounted cash flows resulting from the use and ultimate disposition of the asset.

Income Taxes

The Company has implemented the provisions on Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes" (SFAS 109). SFAS 109 requires that income tax accounts be computed using the liability method. Deferred taxes are determined based upon the estimated future tax effects of differences between the financial reporting and tax reporting bases of assets and liabilities given the provisions of currently enacted tax laws.

Net Loss Per Common Share

The Company computes earnings per share under Financial Accounting Standard No. 128, "Earnings Per Share" (SFAS 128). Net loss per common share is computed by dividing net loss by the weighted average number of shares of common stock and dilutive common stock equivalents outstanding during the year. Dilutive common stock equivalents consist of shares issuable upon conversion of convertible notes and the exercise of the Company's stock options and warrants (calculated using the treasury stock method). During 2006 2005 and 2004, common stock equivalents were not considered in the calculation of the weighted average number of common shares outstanding because they would be anti-dilutive, thereby decreasing the net loss per common share.

Liquidity

As shown in the accompanying financial statements, the Company has incurred a net loss of $13,285,180 from its inception through December 31, 2006. The Company incurred a net loss of $1,486,046 and $ 4,591,107 from operations during the years ended December 31, 2006 and 2005, respectively. The Company's has a net working capital of $2,320,533 with cash and cash equivalents of $2,752,103 at December 31, 2006.

Research and Development

The Company accounts for research and development costs in accordance with the Financial Accounting Standards Board's Statement of Financial Accounting Standards No. 2 ("SFAS 2"), "Accounting for Research and Development Costs. Under SFAS 2, all research and development costs must be charged to expense as incurred. Accordingly, internal research and development costs are expensed as incurred. Third-party research and developments costs are expensed when the contracted work has been performed or as milestone results have been achieved. Company-sponsored research and development costs related to both present and future products are expensed in the period incurred. Total expenditures on research and product development for the years 2006, 2005, and the period

from October 30, 2002 (date of inception) to December 31, 2006 were $484,029, $237,005 and $1,026,597, respectively.

Concentrations of Credit Risk

Financial instruments and related items, which potentially subject the Company to concentrations of credit risk, consist primarily of cash, cash equivalents and related party receivables. The Company places its cash and temporary cash investments with credit quality institutions. At times, such investments may be in excess of the FDIC insurance limit. The Company periodically reviews its trade receivables in determining its allowance for doubtful accounts. There is no allowance for doubtful accounts established as of December 31, 2006.

Comprehensive Income

Statement of Financial Accounting Standards No. 130 ("SFAS 130"), "Reporting Comprehensive Income," establishes standards for reporting and displaying of comprehensive income, its components and accumulated balances. Comprehensive income is defined to include all changes in equity except those resulting from investments by owners and distributions to owners. Among other disclosures, SFAS 130 requires that all items that are required to be recognized under current accounting standards as components of comprehensive income be reported in a financial statement that is displayed with the same prominence as other financial statements. The Company does not have any items of comprehensive income in any of the periods presented.

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, 2006, and changes during the period ended are presented below:

	Options		Weighted Average Exercise Price
Outstanding at December 31, 2005	317,242	$	5.30
Issued	5,596,970	$	0.22
Exercised	--		--
Forfeited or expired	--		--
Outstanding at December 31, 2006	5,914,212	$	0.50
Non-vested at December 31, 2006	2,023,952	$	0.22
Exercisable at December 31, 2006	3,890,260	$	0.64

Aggregate intrinsic value of options outstanding and exercisable at December 31, 2006 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 $0.15 as of December 29, 2006, and the exercise price multiplied by the number of options outstanding. As of December 31, 2006, total unrecognized stock-based compensation expense related to stock options was $264,274. During the year ended December 31, 2006 the Company charged $296,394 to operations related to recognized stock-based compensation expense for employee stock options.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized over the options' vesting period. The Company's pro forma information was as follows:

	Twelve months ended December 31, 2005
Net loss, as reported	$ (4,591,107)
Compensation recognized under under APB 25	--
Compensation recognized under SFAS 123	(83,150)
Pro forma net loss	$ (4,674,257)
Pro forma loss per share	$ (0.07)

Segment Information

Statement of Financial Accounting Standards No. 131, "Disclosures about Segments of an Enterprise and Related Information" ("SFAS 131") establishes standards for reporting information regarding operating segments in annual financial statements and requires selected information for those segments to be presented in interim financial reports issued to stockholders. SFAS 131 also establishes standards for related disclosures about products and services and geographic areas. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions how to allocate resources and assess performance. The information disclosed herein materially represents all of the financial information related to the Company's principal operating segment.

Fair Value of Financial Instruments

The Company measures its financial assets and liabilities in accordance with accounting principles generally accepted in the United States of America. The estimated fair values approximate their carrying value because of the short-term maturity of these instruments or the stated interest rates are indicative of market interest rates.

Prepaid services and other current assets

Prepaid services and other current assets at December 31, 2006 consist of the following:

Prepaid insurance	$ 34,394
Prepaid car lease	43,505
	$ 77,899

Salary advance

The Company has made an advance of salary to one employee in the amount of $1,500.

Deposits and other assets

Deposits and other assets consist of a deposit on leased office space in the amount of $2,260.

F-10

Furniture and Equipment

Furniture and equipment are valued at cost. Depreciation and amortization are provided over the estimated useful lives up to seven years using the straight-line method. The estimated service lives of property and equipment are as follows:

Computer equipment	3 years
Laboratory equipment	3 years
Furniture	7 years

Advertising

The Company follows the policy of charging the costs of advertising to expenses incurred. The Company has not incurred any advertising costs during the years ended December 31, 2006 or 2005.

Reclassifications

Certain reclassifications have been made in prior year's financial statements to conform to classifications used in the current year.

New Accounting Pronouncements

In February 2006, the FASB issued SFAS No. 155. "*Accounting for certain Hybrid Financial Instruments an amendment of FASB Statements No. 133 and 140,"* or SFAS No. 155. SFAS No. 155 permits fair value remeasurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation, clarifies which interest-only strips and principal-only strips are not subject to the requirements of Statement No. 133, establishes a requirement to evaluate interests in securitized financial assets to identify interests that are freestanding derivatives or that are hybrid financial instruments that contain an embedded derivative requiring bifurcation, clarifies that concentrations of credit risk in the form of subordination are not embedded derivatives, and amends SFAS No. 140 to eliminate the prohibition on a qualifying special purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument. SFAS 155 is effective for all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006. We do not expect the adoption of SFAS 155 to have a material impact on our consolidated financial position, results of operations or cash flows.

In March 2006, the FASB issued FASB Statement No. 156, Accounting for Servicing of Financial Assets - an amendment to FASB Statement No. 140. Statement 156 requires that an entity recognize a servicing asset or servicing liability each time it undertakes an obligation to service a financial asset by entering into a service contract under certain situations. The new standard is effective for fiscal years beginning after September 15, 2006. The adoption of SFAS No.156 did not have a material impact on the Company's financial position and results of operations.

In July 2006, the FASB issued Interpretation No. 48 (FIN 48). "*Accounting for uncertainty in Income Taxes"*. FIN 48 clarifies the accounting for Income Taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition and clearly scopes income taxes out of SFAS 5, "*Accounting for Contingencies"*. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company does not expect adoption of this standard will have a material impact on its financial position,

operations or cash flows.

In September 2006 the Financial Account Standards Board (the “FASB”) issued its Statement of Financial Accounting Standards 157, Fair Value Measurements. This Statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles (GAAP), and expands disclosures about fair value measurements. This Statement applies under other accounting pronouncements that require or permit fair value measurements, the Board having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, this Statement does not require any new fair value measurements. However, for some entities, the application of this Statement will change current practice. FAS 157 effective date is for fiscal years beginning after November 15, 2007. The Company does not expect adoption of this standard will have a material impact on its financial position, operations or cash flows.

In September 2006 the FASB issued its Statement of Financial Accounting Standards 158 “Employers’ Accounting for Defined Benefit Pension and Other Postretirement Plans”. This Statement improves financial reporting by requiring an employer to recognize the overfunded or underfunded status of a defined benefit postretirement plan (other than a multiemployer plan) as an asset or liability in its statement of financial position and to recognize changes in that funded status in the year in which the changes occur through comprehensive income of a business entity or changes in unrestricted net assets of a not-for-profit organization. This Statement also improves financial reporting by requiring an employer to measure the funded status of a plan as of the date of its year-end statement of financial position, with limited exceptions. The effective date for an employer with publicly traded equity securities is as of the end of the fiscal year ending after December 15, 2006. The Company does not expect adoption of this standard will have a material impact on its financial position, operations or cash flows

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.

NOTE B - PROPERTY, PLANT AND EQUIPMENT

The Company's property and equipment at December 31, 2006 consists of the following:

Office Equipment	$	34,337
Office Fixtures and Furniture		6,147
		40,484
Accumulated Depreciation		(12,242)
	$	28,242

Depreciation expense included as a charge to income amounted to $2,495, $2,274, and $13,075 for the years ended December 31, 2006 and 2005 and from inception to December 31, 2006, respectively.

NOTE C - ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities at December 31, 2006 are as follows:

Accounts payable and accrued liabilities	$	395,788
Accounts payable - Pre-merger		34,926
Interest payable		5,681
Credit cards		21,374
State income tax payable		3,200
	$	460,969

In addition, $24,814 remains as an amount to be amortized for prepaid insurance for Directors and Officers and liability insurance.

NOTE D - PENALTY FOR LATE REGISTRATION OF SHARES

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.

The Company 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 the Company, pursuant to Rule 477 of Regulation C of the Securities Act of 1933, as amended, applied for an order granting the immediate withdrawal of its 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 $994,574 during the three months ended June 30, 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 the Company 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.

NOTE E - RELATED-PARTY TRANSACTIONS

Cash Advances

In July 2006, the Company received a cash advance from a director in the amount of $25,000. This advance bears interest at the rate of 12% per annum. The Company repaid this cash advance on August 30, 2006 plus accrued interest in the amount of $370.

Credit Cards

The Company has a line of credit with Bank of America for $25,000. Our Chief Executive Officer Michael Wilhelm co-signs this line of credit. At year end December 31, 2006 the Company had an outstanding balance on the credit card of $21,373.

Employment Agreements

PRESIDENT AND CHIEF EXECUTIVE OFFICER:

On August 10, 2005, the Company entered into a new employment agreement with its President and Chief Executive Officer, Michael K. Wilhelm. The employment agreement calls for a salary at the rate of $275,000 per annum. The salary will be subject to adjustment of at least 10% per year at the end of each year. The registrant also agreed to defend and indemnify, to the fullest extent permitted by the registrant's certificate of incorporation and bylaws and the Delaware General Corporation Law, Mr. Wilhelm and hold him harmless against any liability that he incurs within the scope of his employment under the agreement. The agreement also provides for the following various bonus incentives:

i) A target incentive bonus in cash and/or stock if the Company consummates a transaction with any unaffiliated third party such as an equity or debt financing, acquisition, merger , strategic partnership or other similar transaction.

ii) A one time grant of an option to purchase 2,000,000 shares of the Company's common stock at an exercise price equal to the fair market value per share on the date option is granted.

In connection with Mr. Wilhelm's new employment agreement, the Company also entered into a change of control agreement and a severance agreement with him on August 10, 2005.

Under the change of control agreement, Mr. Wilhelm shall be entitled to a continuation of his base salary for a period of 18 months following an involuntary termination, which means, at any time within that period which is one-year from the change of control date (including such date), the termination of the employment of Mr. Wilhelm (i) by the Company without cause or (ii) due to constructive termination, as such terms are defined in the change of control agreement. Further, in the event of an involuntary termination, the agreement provides that the registrant shall pay Mr. Wilhelm a lump sum amount in cash, equal to the sum of (i) any unpaid incentive compensation which has been allocated or awarded to Mr. Wilhelm for a completed fiscal year or other measuring period preceding the date of involuntary termination under any annual or long-term incentive plan and which, as of the date of involuntary termination, is contingent only upon the continued employment of Mr. Wilhelm to a subsequent date, and (ii) a pro rata portion to the date of involuntary termination of the aggregate value of all contingent incentive compensation awards to Mr. Wilhelm for all then uncompleted periods under any such plan. Further, 100% of the unvested portion of each outstanding stock option granted to Mr. Wilhelm shall be accelerated so that they become immediately exercisable upon the date of involuntary termination.

Under the severance agreement, Mr. Wilhelm shall be entitled to a continuation of his base salary for a period of 18 months following an involuntary termination, which means the termination of the employment of Mr. Wilhelm (i) by the Company without cause or (ii) due to constructive termination, as such terms are defined in the severance agreement. Further, in the event of an involuntary termination, the agreement provides that the registrant shall pay Mr. Wilhelm an amount equal to the amount of executive incentive pay (bonus) that he would have received for the year in which the involuntary termination occurred had he met one hundred percent (100%) of the target for such incentive pay. Also, under this agreement, 100% of the unvested portion of each outstanding stock option granted to Mr. Wilhelm shall be accelerated so that they become immediately
exercisable upon the date of involuntary termination.

CHIEF FINANCIAL OFFICER:

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 $1,190,857 net of fees. From March 4, 2005, until December 31, 2005, we will pay an annual salary of $85,000. Thereafter, we will pay an annual salary of $98,000 for the second year ending December 31, 2006 and 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 the Company. Mr. Fermanis also receives 100,000 shares of the Company's common stock, which are earned at the rate of 1/12 or 8,333 per month beginning January 2005. The Company charges to operations the market value of these shares as of the first day of each month. For the twelve months ended December 31, 2006, the Company charged $41,416 to operations for the issuance of 100,000 shares to Mr. Fermanis. This amount is carried in accrued liabilities at December 31, 2006.

SENIOR DIRECTOR OF PRODUCT DEVELOPMENT AND REGULATORY AFFAIRS

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.

Office Lease

During the period from December 1, 2002 through August 31, 2004, the Company leased office space from an entity controlled by the Company's Chief Executive Officer under a sub-let agreement. The rental cost of $2,734 per month was passed through to the Company at the same rental rate charged by the facility's primary landlord.

In July 2004, the Company leased a new office facility from a third party.

NOTE F - NOTES PAYABLE

At December 31, 2006, the Company has outstanding one note payable in the amount of $50,000 to a Director. This note bears interest at the rate of 12% per annum.

NOTE G - CAPITAL STOCK

Common stock

The Company is authorized to issue 10,000,000 shares of preferred stock, par value $0.001 per share. No shares of preferred stock have been issued as of December 31, 2006. The company has authorized 250,000,000 shares of common stock, with a par value of $.001 per share.

In July, 2003 a one for twenty reverse stock split of the Company's common stock was effected . On April 6, 2004, the Company effected a 2 for 1 forward split of its common stock. Total authorized shares and par value remain unchanged. Accordingly, the effect of the reverse and subsequent forward split has been presented in the accompanying financial statement and footnote disclosures. On June 28, 2006, our shareholders voted to approve an amendment to our Certificate of Incorporation, as amended, to increase the number of authorized shares of Common Stock from 100,000,000 to 250,000,000. As of December 31, 2006, the Company has 108,041,897 shares of common stock issued and outstanding.

During the year ended December 31, 2002, the Company issued an aggregate of 1,459,188 shares of common stock to employees and consultants for services in the amount of $ 9,782. All valuations of common stock issued for services were based upon the value of the services rendered, which did not differ materially from the fair value of the Company's common stock during the period the services were rendered. In addition, the Company issued 16,612,276 shares of common stock to its founders in exchange for a proprietary license charged to operations, valued at $ 9,250 (see Note C) . The Company also issued an aggregate of 185,578 shares of common stock in exchange for $ 31,001, net of costs and fees.

During the year ended December 31, 2003, the Company issued an aggregate of 267,594 shares of common stock to consultants for services in the amount of $37,280. All valuations of common stock issued for services were based upon the value of the services rendered, which did not differ materially from the fair value of the Company's common stock during the period the services were rendered. In addition, the Company issued 2,155,104 shares of common stock in exchange for $ 300,000 of previously incurred debt. The Company also issued an aggregate of 383,430 shares of common stock in exchange for $ 65,000 net of costs and fees. In July, 2003, the Company issued 2,368,130 in connection with the Company's acquisition and merger with GPN Network, Inc. (see Note A.)

During the year ended December 31, 2004, the Company issued an aggregate of 5,481,280 shares of common stock to consultants for services in the amount of $2,877,872. All valuations of common stock issued for services were based upon the value of the services rendered, which did not differ materially from the fair value of the Company's common stock during the period the services were rendered. In addition, the Company issued 300,000 shares of common stock as with a fair value of $36,000 as interest on a note payable. In addition, in conjunction with a private placement of stock (see below), the Company issued 6,855,062 shares of common stock in exchange for $ 630,591 of previously incurred debt and accrued interest. In addition, the Company issued 590,000 shares of common stock in exchange for $65,000 of previously issued debt. Total debt exchanged for stock during the year ended December 31, 2004 was $695,591 of debt and interest for 7,745,062 shares of common stock. The Company also sold an aggregate of 18,160,000 shares of common stock in exchange for $ 1,971,045 cash, net of costs and fees. The Company also sold 8,000 shares of common stock for $1,200. The Company also issued an aggregate of 4,900,000 shares of common stock to its investment bankers as fees. The Company also issued 1,257,746 shares of common stock in settlement of $157,219 of accounts payable. In addition, the Company issued an aggregate 1,440,000 shares of common stock to an officer and a director in satisfaction $180,000 of liabilities.

During the year ended December 31, 2005, the Company issued 100,000 shares of common stock to a consultant for services in the amount of $10,000. All valuations of common stock issued for services were based upon the value of the services rendered, which did not differ materially from the fair value of the Company's common stock during the period the services were rendered. In addition, the Company issued 232,153 shares of common stock as with a fair value of $65,003 in exchange for previously issued debt and accrued interest. In addition, 6,600,778 shares of common stock were sold for cash of $1,390,856 net of costs pursuant to a tender offer to certain of the Company’s warrant holders whereby the exercise price of the warrants was temporarily reduced. The Company also issued 80,000 shares of common stock for cash of $4,000 pursuant to the exercise of a warrant at a price of $0.05 per share.

Private Placement of Common Stock

In October 2004, the Company completed a private placement of its common stock (the "Private Placement") whereby the Company sold an aggregate of $2,450,000 worth of units (each a "Unit" and collectively, the "Units") to accredited investors (as defined by Rule 501 under the Securities Act of 1933, as amended) (the transaction is referred to herein as the "Private Placement"). The Company received proceeds of $1,971,845 after costs of the issuance of $298,155.

Included in the $2,450,000 sale was conversion of $180,000 of accrued salary and consulting fees due to an officer and an director of the Company. The number of shares of common stock issued pursuant to the Private Placement was 19,600,000, along with warrants to purchase an additional 9,080,000 shares, plus warrants to purchase an additional

720,000 shares issued to the officer and director. The

Company also issued an additional 4,900,000 shares of common stock to its investment banker as commission. The investment bankers did not acquire any warrants pursuant to this transaction.

Pursuant to the terms of the Private Placement, each Unit was sold for $10,000 (the "Unit Price") and consisted of the following:

(a) a number of shares (the "Shares") of common stock of the Registrant, par value $0.001 per share (the "Common Stock"), determined by dividing: (i) the Unit Price by (ii) $0.125; and

(b) a warrant (each a "Warrant" and collectively, the "Warrants") to purchase, at any time prior to the fifth (5th) anniversary following the date of issuance of the Warrant, a number of shares of Common Stock equal to fifty percent (50%) of the number of Shares included within the Unit, at a price equal to fifty cents ($0.50) per share of Common Stock.

In consideration of the investment, the Company granted to each investor certain registration rights and anti-dilution rights. The Company is obligated to file a registration statement for the shares of common stock issued in the private placement and shares of common stock underlying the warrants issued in the private placement within 30 days of the final closing date of October 26, 2004, or November 25, 2004. The Company is also obligated to effectuate the registration statement within 90 days of the final closing date of October 26, 2004, or January 24, 2005. Failure to meet either of these deadlines results in the Company subject to a penalty of a 2% increase in the number of shares to be registered, or 461,200 shares and warrants to purchase an additional 181,600 shares, for every 30 day period beyond the deadline date. As of the date of the financial statements, the registration statement has not been deemed effective and as a result, the Company has incurred penalties in the amount of $2,061,683 representing the obligation to issue an additional 5,242,307 shares of common stock and warrants to purchase an additional 2,064,187 shares of common stock at a price of $0.50 per share. The accrued penalties in connection with the issuance of the shares of common stock is included in accounts payable and accrued expenses at December 31, 2005.

In conjunction with raising capital through the private placement of our common stock, the Company issued a warrant that has registration rights for the underlying shares. As the contract must be settled by the delivery of registered shares and the delivery of the registered shares is not controlled by the Company, pursuant to EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock", the net value of the 9,800,000 warrants and an additional 2,064,187 penalty warrants at their respective dates of issuance has been recorded as a warrant liability on the balance sheet ($638,838) and the change in fair value from the date of issuance to December 31, 2005 has been included in other income (expense). The assumptions used in the Black Scholes model are as follows: (1) dividend yield of 0%; (2) expected volatility of 79%, (3) risk-free interest rate of 4.5%, and (4) expected life of 5 years. Upon the registration statement being declared effective, the fair value of the warrant on that date will be reclassified to equity.

For the year ended December 31, 2006 the fair value of the warrants issued with registration rights decreased by approximately $123,505 to $182,236 at August 21, 2006 and is recognized in other income (expense). On August 21, 2006, the Company issued the 1,634,400 warrants to purchase shares of common stock in satisfaction of the penalty due to investors for the late registration of shares.

In October 2004, the Company converted certain notes payable with an aggregate principal amount of $558,500 plus accrued interest of $56,757 for a total of $630,328 into Units with terms identical to those provided to investors in the Private Placement. The number of shares of common stock issued via these note conversions was 6,694,149 along with warrants to purchase an additional 3,347,076 shares (see Note H).

Also in October 2004, the Company entered into a settlement agreements with certain creditors whereby for full and complete satisfaction of claims totaling an aggregate of $157,219 the Company issued Units with terms identical to those provided to investors in the Private Placement. The number of shares of common stock issued via these creditor conversions was 1,257,746, along with warrants to purchase an additional 628,873 shares.

On January 24, 2005, the Company made a tender offer to certain of the Company's shareholders whereby the exercise price of certain warrants issued in October 2004 (the "Warrants") would be reduced from $0.50 to $0.20 per share. In March 2005, 6,600,778 shares of common stock were sold pursuant to this offer for aggregate proceeds of $1,320,156 less costs of $129,300.

In June 2005, the Company issued 80,000 shares of common stock pursuant to the Exercise of a warrant at a price of $0.05 per share.

In July 2005, the Company issued 232,153 shares of common stock at a price of $0.28 per share pursuant to the conversion of a note payable (see Note F.)

In August 2005, the Company issued 100,000 shares of common stock pursuant to an agreement with a service provider. The fair value of these shares of $10,000 was amortized over the life of the contract, from July 2004 to July 2005.

In March 2006, the Company issued 100,000 shares of common stock to its Chief Financial Officer for a total compensation of $41,416 These shares were earned, and accrued during the year ended December 31, 2006. share to an investor for the conversion of accrued interest.

In May 2006, the Company issued 34,464 shares of S-8 common stock at $0.125 per share to a consultant for services provided for business development.

In May 2006, the Company issued 19,288 shares of common stock at $0.125 per share to an investor for the conversion of accrued interest.

In May 2006, the Company issued 16,324 shares of common stock at $0.125 per share to an investor for the conversion of accrued interest.

In May 2006, the Company issued 13,454 shares of common stock at $0.10 per share to an investor for the conversion of accrued interest.

In June 2006, the Company issued 5,000 shares of common stock at $0.09 per share for the exercise of warrants by an investor.

In August 2006, the Company issued 4,150,798 shares of common stock for the penalty for late registration of shares, which were previously accrued.

During the fourth quarter of 2006, we completed a private placement, whereby we sold an aggregate of $5,482,600 worth of units to accredited investors. Each unit was sold for $25,000 and consisted of (a) a number of shares of our common stock determined by dividing the unit price by $0.16, and (b) a five-year warrant to purchase a number of shares of our common stock equal to 50% of the number of shares included within the unit, at $0.50 per share. We issued in the private placement an aggregate of 34,266,250 shares of our common stock and warrants to purchase 17,133,125 shares of our common stock. In consideration of the investment, we granted to each investor certain registration rights and anti-dilution rights. We agreed that not before 180 days after the closing of the private placement and not later than 190 days thereafter, that we will file with the SEC a registration statement to register these shares along with the shares underlying these warrants. In the event that we fail to comply with the filing deadline, there shall be a 1% penalty for each 30 day period (or pro rata portion thereof) paid to each investor in cash or additional shares. This penalty amounts to an aggregate of 342,662 shares and 171,331 warrants per 30 day period until a registration statement that includes these shares and warrants is filed or 12 months. As of December 31, 2006, we are not subject to any penalty. As placement agent for the private placement, Joseph Stevens & Co., Inc. and its designees received 5,482,600 shares of our common upon the closing of the private placement. As of December 31, 2006, the shares to be issued to Joseph Stevens & Co. were not issued and are included in common stock subscribed.

The Company has evaluated the Registration Rights Agreement related to the December 2006 private placement, specifically the 1% liquidated damages clause under EITF Issue No. 00-19 to determine whether the warrants issued with the private placement should be classified as a liability versus equity. According to EITF Issue No. 00-19, paragraph 16 "If a settlement alternative includes a penalty that would be avoided by a company under other settlement alternatives, the uneconomic settlement alternative should be disregarded in classifying the contract. In the case of delivery of unregistered shares, a discount from the value of the corresponding registered shares that is a reasonable estimate of the difference in fair values between registered and unregistered shares (that is, the discount reflects the fair value of the restricted shares determined using commercially reasonable means) is not considered a penalty."

The Company concluded that the 12% cap added to the liquidated damages clause, represents an economically reasonable difference between registered and unregistered shares. As a result, the Company has not classified the fair value of the warrants issued related to the private placement as a liability.

The Company completed the private placement with the following three transactions:

On October 4, 2006, the Company completed the closing of a private placement of its common stock whereby the Company sold an aggregate of $2,276,500 worth of units to accredited investors (as defined by Rule 501 under the Securities Act of 1933, as amended). The Company received proceeds of $1,841,724 after costs of $434,776. The number of share of common stock issued pursuant to the Private Placement was 14,228,125, along with warrants to purchase an additional 7,114,063 shares.

On October 26, 2006, the Company completed the closing of a private placement of its common stock whereby the Company sold an aggregate of $2,697,100 worth of units to accredited investors (as defined by Rule 501 under the Securities Act of 1933, as amended). The Company received proceeds of $2,344,020 after costs of $353,080. The number of share of common stock issued pursuant to the Private Placement was 16,856,875, along with warrants to purchase an additional 8,428,438 shares.

On December 6, 2006, the Company completed the closing of a private placement of its common stock whereby the Company sold an aggregate of $509,000 worth of units to accredited investors (as defined by Rule 501 under the Securities Act of 1933, as amended). The Company received proceeds of $427,805 after costs of $81,195. The number of share of common stock issued pursuant to the Private Placement was 3,181,250, along with warrants to purchase an additional 1,590,625 shares.

Shares and warrants issued due to late filing of registration statement

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.

The Company 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 the Company, pursuant to Rule 477 of Regulation C of the Securities Act of 1933, as amended, applied for an order granting the immediate withdrawal of its 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 $994,574 during the three months ended June 30, 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 the Company 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.

NOTE H - STOCK OPTIONS AND WARRANTS

Employee Stock Options

The Company has adopted the 2003 Stock Option, Deferred Stock and Restricted Stock Plan (the “Plan”) which authorizes the Board of Directors in accordance with the terms of the Plan, among other things, to grant incentive stock options as defined by Section 422(b) if the Internal Revenue Code, nonstatutory stock options (collectively, the “Stock Options”) and awards of restricted stock and deferred stock and to sell shares of common stock of the Company (“Common Stock”) pursuant to the exercise of such stock options for up to an aggregate of 6,465,316 shares. The options will have a term not to exceed ten years from the date of the grant.

On June 28, 2006, our shareholders voted to (i) approve an amendment to our Certificate of Incorporation, as amended, to increase the number of authorized shares of Common Stock from 100,000,000 to 250,000,000 and (ii) approve an amendment to our 2003 Stock Option, Deferred Stock and Restricted Stock Plan to increase the number of shares of our Common Stock reserved and available for issuance under the Plan from 3,600,000 to 20,000,000.

Through December 31, 2002, GPN had granted pre-merger stock options to certain employees and consultants which are exercisable over various periods through March 2010. These stock options are currently held by the Company outside of this Plan.

In July 2006, the Company issued options to purchase 1,893,970 shares of common stock to our Chief Executive Officer. The options vest 50% after ninety days of continued employment and the balance in equal monthly installments for 12 months thereafter.

In September 2006, the Company issued options to purchase 3,500,000 shares of common stock to our Chief Executive Officer. The options vest 50% after thirty days of continued employment with the balance in equal monthly installments for one year thereafter.

In October 2006, the Company issued options to purchase 200,000 shares of common stock to an employee.

As of December 31, 2006, total unrecognized stock-based compensation expense related to stock options was $264,274. During the year ended December 31, 2000 the Company charged $296,394 to operations related to recognized stock-based compensation expense for employee stock options.

The following table summarizes the changes in options outstanding and the related prices for the shares of the Company's common stock issued to employees of the Company under a non-qualified employee stock option plan.

	Options Outstanding			Options Exercisable		
Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Remaining Contractual Life (years)
$25.00	63,212	3.25	$ 25.00	63,212	3.25
0.231	1,896,970	4.54	0.231	1,222,416	4.54
0.20-0.22	3,700,000	4.71	0.20-0.22	2,350,602	4.71

0.31	1,000	4.00	0.31	1,000	4.00
0.33	103,030	3.64	0.33	103,030	3.64
0.44	150,000	3.50	0.44	150,000	3.50
	5,914,212			3,890,260	

Options not vested are not exercisable. Transactions involving stock options issued to employees are summarized as follows:

	Number of Shares		Weighted Average Price Per Share
Outstanding at December 31, 2003	63,212	$	25.00
Granted	--		--
Exercised	--		--
Expired	--		--
Outstanding at December 31, 2004	63,212	$	25.00
Granted	254,030		0.39
Exercise	--		--
Expired	--		--
Outstanding at December 31, 2005	317,242	$	5.30
Granted	5,596,970		0.22
Exercise	--		--
Expired	--		--
Outstanding at December 31, 2006	5,914,212	$	0.50

Warrants

The following table summarizes the changes in warrants outstanding and the related prices for the shares of the company's common stock issued to non-employees of the Company. These warrants were granted in lieu of cash for compensation for services performed of financing expenses and in connection with placement of convertible debentures.

Warrants Outstanding			Warrants Exercisable		
Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Remaining Contractual Life (years)
$ .05-.10	594,780	2.41	$ .05-.10	594,780	2.41
.125-.22	1,014,319	2.16	.125-.22	1,014,319	2.16
.23-.56	28,316,934	4.03	.23-.56	28,316,934	4.03
1.00	688,964	1.91	1.00	688,964	1.91
2.00	36,550	2.32	2.00	36,550	2.32
	30,651,547	3.88		30,651,547	3.88

Transactions involving warrants are summarized as follows:

	Number of Shares (post-split)	Weighted Average Price Per Share (post-split)
Outstanding at December 31, 2003	832,510	$ 0.82
Granted	16,831,199	0.47
Exercised	(6,600,778)	0.50
Cancelled or expired	--	--
Outstanding at December 31, 2004	11,062,931	$ 0.48
Granted	757,464	0.44
Exercised	(80,000)	0.05
Canceled or expired	(123,526)	2.00
Outstanding at December 31, 2005	11,616,869	$ 0.46
Granted	19,365,678	0.32
Exercised	(5,000)	0.09
Cancelled or expired	(326,000)	1.00
Outstanding at December 31, 2006	30,651,547	$ 0.37

The estimated value of the compensatory warrants granted to non-employees in exchange for services and financing expenses was determined using the Black-Scholes pricing model and the following assumptions:

	2006	2005
Significant assumptions (weighted-average):		
Risk-free interest rate at grant date	4.5% to 4.75%	3.75%
Expected stock price volatility	92% to 73%	93% to 179%
Expected dividend payout	--	--
Expected option life-years (a)	3 to 5	3 to 5

At December 31, 2002, the Company had outstanding warrants to purchase 26,939 shares (post-split) of common stock at $0.835 per share (post-split).

During the twelve months ended December 31, 2003, the Company issued warrants to purchase 169,572 shares (post-split) of common stock at prices ranging from $0.125 to $1.00 per share (post-split) to eight service providers. The Company valued the warrants using the Black-Scholes calculation model, and the warrants were deemed to have a combined value of $85,860. This amount was charged to expense on the Company's financial statements for the twelve months ending December 31, 2003.

In October 2003, pursuant to the Amended Note agreements, the Company issued the Amended Note Warrants to purchase 245,000 shares (post-split) of its common stock at a price of $1.00 per share (post-split). The Company valued the Amended Note Warrants using the Black-Scholes calculation model, and the warrants were deemed to have a combined value of $189,937. This amount was recorded as a discount to the Amended Notes and an addition to paid-in capital, and was charged to expense over the term of the notes, or 180 days. During the twelve months ended December 31, 2003, the Company recognized $84,169 of expense in relation to these warrants. During the twelve months ended December 31, 2004, the remaining $105,768 was charged to operations.

In October, November, and December 2003, pursuant to the Fourth Quarter Note agreements, the Company issued the Fourth Quarter Company Warrants to purchase 391,000 shares (post-split) of its common stock at a price of $1.00 per share (post-split).

As an additional incentive to investors in the Secured Convertible Promissory Notes, the Company provided five-year warrants (the "Secured Note Warrants") to purchase that number of shares of common stock equal to one-half the initial principal amount of the Secured Convertible Promissory Notes. For example, an investor who purchased a $10,000 Secured Convertible Promissory Note would receive a warrant to purchase 8,979 shares (post-split) of common stock. The exercise price of the Secured Note Warrants is equal to 60% of the price per share paid by investors in a future equity financing (the "Reorganization Financing"). The Secured Note Warrants are not considered granted until the completion of the Reorganization Financing. In accordance with EITF 00-27, because the Reorganization Financing had not occurred at December 31, 2003, the Company ascribed no value to the Secured Note Warrants at December 31, 2003. At the time of the first closing of the Private Placement in October 2004, warrants to purchase a total of 444,490 shares (post-split) of common stock at $0.075 per share (post-split) were issued under the Secured Note Warrants. The value of these warrants was computed utilizing the Black-Scholes valuation model, and the total value of these warrants, or $112,562 was charged to operations during the twelve months ended December 31, 2004.

The Company has outstanding warrants to purchase 250,000 shares of common stock at $0.30 per share which were issued in 2002 by its predecessor company GPN Network.

In April through June 2004, the Company issued warrants to purchase 32,500 shares (post-split) at price ranging from $0.25 to $2.00 to consultants for services performed. The Company valued these warrants using the Black-Scholes valuation model, and charged the amount of $8,318 to operations during the twelve months ended December 31, 2004.

In May 2004, the Company issued a warrant to its President and a warrant to a Director, each warrant to purchase 500,000 shares (post-split) of common stock at a price of $0.25 per share (post-split). The warrants were issued as performance bonuses. The Company valued these warrants using the Black-Scholes model, and charged the amount of $134,604 for each warrant, or a total of $269,208, to operations during the twelve months ended December 31, 2004.

In October 2004, the Company issued a warrant to its President to purchase 448,980 shares (post-split) at a price of $0.125 per share (post-split) as a performance bonus for achieving certain objectives. The Company valued this warrant using the Black-Scholes valuation model, and charged the amount of $112,697 to operations during the twelve months ended December 31, 2004.

In November and December 2004, the Company issued a warrant to purchase 50,000 shares (post-split) of its common stock at a price of $0.125 per share (post-split) and a warrant to purchase 10,000 shares (post-split) of its common stock at a price of $0.075 per share (post-split) to two members of its advisory boards. The Company valued these warrants using the Black-Scholes valuation model, and charged the aggregate amount of $16,348 to operations during the twelve months ended December 31, 2004.

In October 2004, the Company issued warrants to purchase 9,080,000 shares (post-split) of its common stock at a price of $0.50 per share (post-split) to the investors in its private placement of equity securities. The Company allocated $607,922 of the total proceeds of $1,971,845 to the warrants, and charged this amount to additional paid-in capital during the twelve months ended December 31, 2004.

In October 2004, the Company issued warrants to purchase an aggregate of 720,000 shares (post-split) of its common stock at a price of $0.50 per share (post-split) to the an officer and a director for converting a total of $180,000 of amounts owed to these individuals for accrued salary and accrued consulting fees. The Company allocated $56,067 of the total proceeds of $180,000 to the warrants, and charged this amount to additional paid-in capital during the twelve months ended December 31, 2004.

In October 2004, the Company issued warrants to purchase 3,347,076 shares (post-split) of its common stock at a price of $0.50 per share (post-split) to the convertible note holders who invested its private placement of equity securities via conversion of their notes. The Company allocated $191,111 of the total amount converted of $615,328 to the warrants, and charged this amount to additional paid-in capital during the twelve months ended December 31, 2004.

In October 2004, the Company issued warrants to purchase 628,873 shares (post-split) of its common stock at a price of $0.50 per share (post-split) to the vendors who invested in its private placement of equity securities via conversion of amounts owed to them by the Company. The Company allocated $48,579 of the total amount converted of $157,219 to the warrants, and charged this amount to additional paid-in capital during the twelve months ended December 31, 2004.

In April through June 2004, the Company issued warrants to purchase 77,500 shares (post-split) of its common stock at prices ranging from $0.25 to $2.00 per share (post-split) to certain investors as additional incentive under notes payable agreements. The Company valued these warrants using the Black-Scholes model, and charged the amount of $17,915 to additional paid-in capital during the twelve months ended December 31, 2004.

In July and August 2004, the Company issued warrants to purchase 744,280 shares (post-split) of its common stock at prices ranging from $0.05 to $2.00 per share (post-split) to certain investors as additional incentive under notes payable agreements. The Company valued these warrants using the Black-Scholes model, and charged the amount of $72,252 to additional paid-in capital during the twelve months ended December 31, 2004.

During the three months ended March 31, 2005, the Company issued warrants to purchase 268,033 shares of common stock at prices ranging from $0.125 to $1.00 to consultants for services performed. The Company valued these warrants using the Black-Scholes valuation model, and charged the amount of $137,049 to operations during the twelve months ended December 31, 2005.

During the three months ended June 30, 2005, the Company issued warrants to purchase 366,814 shares of common stock at prices ranging from $0.038 to $1.00 per share to consultants and advisory board members. The Company also cancelled warrants to purchase 123,530 shares of common stock at a price of $2.00 per share. The Company valued these issuance and cancellations using the Black-Scholes valuation model, and charged the amount of $103,772 to operations during the twelve months ended December 31, 2005.

Also during the three months ended June 30, 2005, warrants to purchase 80,000 shares of common stock at a price of $0.05 per share were exercised.

During the three months ended September 30, 2005, the Company issued warrants to purchase 77,250 shares of common stock at prices ranging from $0.125 to $1.00 per share to consultants and advisory board members. The Company valued these warrants using the Black-Scholes valuation model, and charged the amount of $20,491 to operations during the twelve months ended December 31, 2005.

In October and December 2005, the Company issued warrants to purchase 62,467 shares of common stock at prices ranging from $0.125 to $1.00 to consultants and advisory board members for services provided. The Company valued these warrants using the Black-Scholes valuation model, and charged the amount of $18,399 to operations during the twelve months ended December 31, 2005.

During the three months ended March 31, 2006, the Company issued warrants to purchase 61,500 shares of common stock at prices ranging from $0.125 to $1.00 to consultants for services performed. The Company valued these warrants using the Black-Scholes valuation model, and charged the amount of $8,399 to operations during the three months ended March 31, 2006.

During the three months ended June 30, 2006, the Company issued warrants to purchase 84,653 shares of common stock at prices ranging from $0.20 to $1.00 to consultants for services performed. The Company valued these warrants using the Black-Scholes valuation model, and charged the amount of $8,819 to operations during the three months ended June 30, 2006.

Also during the three months ended June 30, 2006, an investor exercised a warrant to purchase 5,000 shares of the Company's common stock at a price of $0.09 per share.

During the three months ended September 30, 2006, the Company issued warrants to purchase 46,000 shares of common stock at prices ranging from $0.20 to $1.00 to consultants for services performed. The Company valued these warrants using the Black-Scholes valuation model, and charged the amount of $3,495 to operations during the three months ended September 30, 2006.

During the three months ended September 30, 2006, the Company issued warrants to purchase 300,000 shares of common stock at $0.25 to our Chief Executive Officer, Michael Wilhelm. The Company valued these warrants using the Black-Scholes valuation model, and charged the amount of $41,278 to operations during the three months ended September 30, 2006.

Also, during the three months ended September 30, 2006, the Company issued warrants to purchase 62,500 shares of common stock at $0.158 to our Chief Financial Officer, John Fermanis per the terms of his employment agreement. The Company valued these warrants using the Black-Scholes valuation model, and charged the amount of $9,596 to operations during the three months ended September 30, 2006.

During the three months ended September 30, 2006, the Company issued warrants to purchase an additional 1,634,400 shares of common stock in satisfaction of the penalty due to investors for the late registration of shares. The Company had accrued the value of these warrants using the Black-Scholes valuation model, and relieved the accrued liability of $258,986.

In October 2006, the Company issued warrants to purchase 7,114,063 shares of its common stock at a price of $0.50 per share to the investors in its first closing of private placement of equity securities. The Company allocated $804,003 of the total proceeds of $1,057,640 to the warrants, and charged this amount to additional paid-in capital during the twelve months ended December 31, 2006.

In October 2006, the Company issued warrants to purchase 8,428,437 shares of its common stock at a price of $0.50 per share to the investors in its second closing of private placement of equity securities. The Company allocated $759,384 of the total proceeds of $2,344,020 to the warrants, and charged this amount to additional paid-in capital during the twelve months ended December 31, 2006.

In October 2006, the Company issued warrants to purchase 1,590,625 shares of its common stock at a price of $0.50 per share to the investors in its final closing of private placement of equity securities. The Company allocated $162,952 of the total proceeds of $427,805 to the warrants, and charged this amount to additional paid-in capital during the twelve months ended December 31, 2006.

During the three months ended December 31, 2006, the Company issued warrants to purchase 43,500 shares of common stock at prices ranging from $0.20 to $1.00 to consultants for services performed. The Company valued these warrants using the Black-Scholes valuation model, and charged the amount of $1,974 to operations during the three months ended December 31, 2006.

NOTE I - COMMITMENTS AND CONTINGENCIES

Office Leases

Our corporate headquarters are currently located at 4021 N. 75th Street, Suite 201, Scottsdale, Arizona 85251, where we have leased approximately 1,800 square feet of office space through September 30, 2007. Our rent expense is $2,320 per month in year one and will increase to $2,380 in year two. 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.

Rent expense amounted to $28,622 for the years ended December 31, 2006, $27,785 for the year ended December 31, 2005, and $131,561 for the period from October 30, 2002 (inception) through December 31, 2006.

Employment and Consulting Agreements

The Company has employment agreements with the President and Chief Executive Officer (See Note E). In addition to salary and benefit provisions, the agreements include non-disclosure and confidentiality provisions for the protection of the Company's proprietary information. The Company also has a severance agreement and a change of control agreement in place with its President and Chief Executive Officer.

The Company also has an employment agreement with its Chief Financial Officer and Senior Director, Product Development and Regulatory Affairs which provide salary and benefit provisions.

The Company has consulting agreements with outside contractors to provide marketing and financial and scientific advisory services. The Agreements are generally for a term of 12 months from inception and renewable automatically from year to year unless either the Company or Consultant terminates such engagement by written notice.

Litigation

The Company is subject to other legal proceedings and claims, which arise in the ordinary course of its business. Although occasional adverse decisions or settlements may occur, the Company believes that the final disposition of such matters should not have a material adverse effect on its financial position, results of operations or liquidity.

NOTE J - INCOME TAXES

The Company has adopted Financial Accounting Standard No. 109 which requires the recognition of deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statement or tax returns. Under this method, deferred tax liabilities and assets are determined based on the difference between financial statements and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Temporary differences between taxable income reported for financial reporting purposes and income tax purposes are insignificant.

For income tax reporting purposes, the Company's aggregate unused net operating losses approximate $6,100,000 which expire through 2027, subject to limitations of Section 382 of the Internal Revenue Code, as amended. The deferred tax asset related to the carryforward is approximately $2,135,000. The Company has provided a valuation reserve against the full amount of the net operating loss benefit, because in the opinion of management based upon the earning history of the Company, it is more likely than not that the benefits will not be realized.

Components of deferred tax assets as of December 31, 2006 are as follows:
Non Current:

Net operating loss carryforward	$ 2,135,000
Valuation allowance	(2,135,000)
Net deferred tax asset	$ --

NOTE K - SUBSEQUENT EVENTS

On January 1, 2007 we entered into a three month agreement with an investor relations firm. For services provided the consulting firm is to receive a monthly cash fee. In addition to the cash fee, we issued to the firm 100,000 restricted shares of common stock.

On January 1, 2007 we entered into a six month agreement with a second investor relations firm. For services provided the consulting firm is to receive a monthly cash fee. In addition to the cash fee, we issued to the firm 400,000 restricted shares of common stock.

On January 1, 2007 we entered into a two year employment agreement for a Market and Regulatory Affairs Analyst. In addition to the monthly cash salary the employee received statutory options with a term of five years to purchase 100,000 shares of common stock of the Company. The options are exercisable at $0.128 per share and vest in equal amounts quarterly over the term of the contract. The employee also received 298,039 common shares of stock for past services provided between June 2006 and December 2006. The amount of $44,706 was accrued at December 31, 2006 for this past service.

ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 8A. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

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

As of the end of the period covered by this Annual Report, we conducted an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of our disclosure controls and procedures (as defined in Rules 13a-15(e) of the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in enabling the Company to record, process, summarize and report information required to be included in the Company's periodic SEC filings within the required time period.

Changes in internal controls

There have been no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or 15d-15 under the Exchange Act that occurred during the quarter ended December 31, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 8B. OTHER INFORMATION

None.

PART III

ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(A) OF THE EXCHANGE ACT

The information required by this Item 9 is incorporated by reference from our definitive proxy statement on Schedule 14A which will be filed before the end of the 120-day period immediately following the end of our 2006 fiscal year, or, if our definitive proxy statement is not filed within that time, the information will be filed as part of an amendment to this Annual Report on Form 10-KSB/A, not later than the end of the 120-day period.

ITEM 10. EXECUTIVE COMPENSATION

The information required by this Item 10 is incorporated by reference from our definitive proxy statement on Schedule 14A which will be filed before the end of the 120-day period immediately following the end of our 2006 fiscal year, or, if our definitive proxy statement is not filed within that time, the information will be filed as part of an amendment to this Annual Report on Form 10-KSB/A, not later than the end of the 120-day period.

ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by this Item 11 is incorporated by reference from our definitive proxy statement on Schedule 14A which will be filed before the end of the 120-day period immediately following the end of our 2006 fiscal year, or, if our definitive proxy statement is not filed within that time, the information will be filed as part of an amendment to this Annual Report on Form 10-KSB/A, not later than the end of the 120-day period.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

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

ITEM 13. EXHIBITS

EXHIBITS

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

3.1(b)	Certificate of Amendment filed with the Delaware Secretary of State on February 3, 1992 (incorporated by reference to exhibit 3.1(b) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(c)	Certificate of Amendment filed with the Delaware Secretary of State on November 23, 1992 (incorporated by reference to exhibit 3.1(c) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(d)	Certificate of Amendment filed with the Delaware Secretary of State on December 15, 1994 (incorporated by reference to exhibit 3.1(d) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(e)	Certificate of Amendment filed with the Delaware Secretary of State on November 7, 1995 (incorporated by reference to exhibit 3.1(e) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(f)	Certificate of Amendment filed with the Delaware Secretary of State on December 30, 1996 (incorporated by reference to exhibit 3.1(f) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(g)	Certificate of Amendment filed with the Delaware Secretary of State on November 8, 2000 (incorporated by reference to exhibit 3.1(h) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.2	Amended and Restated Bylaws of the Registrant dated as of January 1, 2002 (incorporated by reference to exhibit 3(b) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
4.1	Specimen Common Stock Certificate (incorporated by reference to exhibit 4.1 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).

Exhibit Number	Description of Exhibit
4.2	2003 Stock Option, Deferred Stock and Restricted Stock Plan (incorporated by reference to exhibit 4.1 of the Registrant's registration statement on Form S-8 (file no. 333-113511) filed with the Securities and Exchange Commission on March 11, 2004).
4.3	Form of Warrant by and between the Registrant and each of the Investors or Creditors, as the case may be, who entered into an Agreement filed as Exhibit 10.6, 10.7, 10.8 or 10.9 herewith (incorporated by reference to exhibit 4.1 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2004).
4.4	Form of Registration Rights (Annex A to Subscription Agreement) by and between the Registrant and each of the Investors who entered into the Agreements filed as Exhibits 10.6 and 10.8 herewith (incorporated by reference to exhibit 4.2 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2004).
4.5	Form of Anti-Dilution Rights (Annex B to Subscription Agreement) by and between the Registrant and each of the Investors who entered into the Agreements filed as Exhibits 10.6 and 10.8 herewith (incorporated by reference to exhibit 4.3 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2004).
4.6	Promissory Note issued from the Registrant to SBM Certificate Company as of April 28, 2004 (incorporated by reference to exhibit 4.6 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).
4.7	Form of Warrant by and between the Registrant and each of the investors who entered into the Subscription Agreements filed as Exhibits 10.18, 10.19 and 10.20 herewith (incorporated by reference from Exhibit 4.1 to the Quarterly Report on Form 10-QSB as filed with the Securities and Exchange Commission on November 14, 2006).
10.1	License Agreement dated December 16, 2002 among ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, David Harris and Mark Witten (incorporated by reference to exhibit 10.4 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).
10.1(a)	First Amendment to License Agreement dated December 20, 2002 among ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, David Harris and Mark Witten (incorporated by reference to exhibit 10.4(a) of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).
10.1(b)	Second Amendment to License Agreement dated June 26, 2003 among ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, David Harris and Mark Witten (incorporated by reference to exhibit 10.4(b) of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).
10.1(c)	Assignment Agreement dated February 23, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Mark Witten (incorporated by reference to exhibit 10.4(c) of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on July 20, 2005).
10.1(d)	

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

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

10.1(f) Assignment Agreement dated November 7, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Mark Witten (incorporated by reference to exhibit 10.4(f) of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).

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

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

10.2 Lease Agreement dated July 1, 2004 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, and The Clayton Companies (incorporated by reference to exhibit 10.5 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).

Exhibit Number	Description of Exhibit
10.3	Form of Subscription Agreement entered into as of October 13, 2004 between the Registrant and each of the Investors set forth on the Schedule of Investors thereto (incorporated by reference to exhibit 10.1 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2004).
10.4	Form of Settlement Agreement entered into as of October 13, 2004 between the Registrant and each of the Creditors set forth on the Schedule of Creditors thereto (incorporated by reference to exhibit 10.2 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2004).
10.5	Form of Subscription Agreement entered into as of October 26, 2004 between the Registrant and each of the Investors set forth on the Schedule of Investors thereto (incorporated by reference to exhibit 10.1 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 27, 2004).
10.6	Form of Settlement Agreement entered into as of October 26, 2004 between the Registrant and each of the Creditors set forth on the Schedule of Creditors thereto (incorporated by reference to exhibit 10.2 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 27, 2004).
10.7	Employment Agreement dated February 15, 2005 between the Registrant and John N. Fermanis (incorporated by reference to exhibit 10.10 of the Registrant's Amendment No. 1 on Form 10-K/A to its annual report for the year ended December 31, 2004).
10.8	Employment Agreement dated August 10, 2005 by and between the Registrant and Michael K. Wilhelm (incorporated by reference to exhibit 10.1 of the Registrant's quarterly report on Form 10-QSB for the three months ended September 30, 2005).
10.9	Change of Control Agreement dated August 10, 2005 by and between the Registrant and Michael K. Wilhelm (incorporated by reference to exhibit 10.2 of the Registrant's quarterly report on Form 10-QSB for the three months ended September 30, 2005).
10.10	Severance Agreement dated November 7, 2005 by and between the Registrant and Michael K. Wilhelm (incorporated by reference to exhibit 10.3 of the Registrant's quarterly report on Form 10-QSB for the three months ended September 30, 2005).
10.11	Authorization for Regulatory Contact dated November 7, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, and Synergos, Inc. (incorporated by reference to exhibit 10.14 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).
10.12	Proforma invoice/quotation dated November 7, 2005 from Sigma-Aldrich, Inc. to ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant (incorporated by reference to exhibit 10.15 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 16, 2005).

50

Exhibit Number	Description of Exhibit
10.13	Letter of acceptance dated October 2, 2003, from Huntingdon Life Sciences to ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant (incorporated by reference to exhibit 10.16 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).
10.14	Price Quotation dated June 27, 2003 received by ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant from AppTec Laboratory Services (incorporated by reference to exhibit 10.17 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).
10.15	Consulting Agreement dated March 15, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Dr. Hal Siegel, Ph.D. (Siegel Consultancy) (incorporated by reference to exhibit 10.18 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).
10.16	Consulting Agreement dated November 3, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Dr. Jack Caravelli, Ph.D (incorporated by reference to exhibit 10.19 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).
10.17	Consulting Agreement dated July 29, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Dr. Kelly McQueen, MD, MPH (incorporated by reference to exhibit 10.20 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).
10.18	Form of Subscription Agreement entered into as of December 6, 2006 between the Registrant and each of the Investors set forth on the Schedule of Investors contained therein (incorporated by reference from Exhibit 10.1 to the Report on Form 8-K as filed with the Securities and Exchange Commission on December 7, 2006).
10.19	Form of Subscription Agreement entered into as of October 4, 2006 between the Registrant and each of the Investors set forth on the Schedule of Investors contained therein. (incorporated by reference from Exhibit 10.2 to the Quarterly Report on Form 10-QSB as filed with the Securities and Exchange Commission on November 14, 2006).
10.20	Form of Subscription Agreement entered into as of October 26, 2006 between the Registrant and each of the Investors set forth on the Schedule of Investors contained therein (incorporated by reference from Exhibit 10.2 to the Quarterly Report on Form 10-QSB as filed with the Securities and Exchange Commission on November 14, 2006).
21.1	Subsidiaries of Registrant (incorporated by reference to exhibit 21.1 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).
23.1	Consent of Russell Bedford Stefanou Mirchandani LLP
31.1	Certification of Chief Executive Officer pursuant to Item 601(b)(31) of Regulation S-B, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

51

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

---

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

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth fees billed to us by our auditors during the fiscal years ended December 31, 2006 and December 31, 2005 for: (i) services rendered for the audit of our annual financial statements and the review of our quarterly financial statements, (ii) services by our auditor that are reasonably related to the performance of the audit or review of our financial statements and that are not reported as Audit Fees, (iii) services rendered in connection with tax compliance, tax advice and tax planning, and (iv) all other fees for services rendered.

	December 31, 2006	December 31, 2005
(i) Audit Fees	$ 58,856	$ 67,000
(ii) Audit Related Fees	--	--
(iii) Tax Fees	--	10,000
(iv) All Other Fees	4,795	--
Total fees	$ 63,651	$ 77,000

AUDIT FEES. Consists of fees billed for professional services rendered for the audit of the Company's consolidated financial statements and review of the interim consolidated financial statements included in quarterly reports and services that are normally provided by the Company's certifying accountant in connection with statutory and regulatory filings or engagements.

TAX FEES. Consists of all services performed by the independent auditor’s tax personnel, except those related to the audit of financial statements, and include tax compliance, tax consulting, tax planning and non-recurring projects.

ALL OTHER FEES. Consists of fees billed for professional services performed by the independent auditors related to the review of and consent to the Company’s SEC Form S-8.

POLICY ON AUDIT COMMITTEE PRE-APPROVAL OF AUDIT AND PERMISSIBLE NON-AUDIT SERVICES OF INDEPENDENT AUDITORS

We currently do not have a designated Audit Committee, and accordingly, the our Board of Directors' policy is to pre-approve all audit and permissible non-audit services provided by the independent auditors. These services may include audit services, audit-related services, tax services and other services. Pre-approval is generally provided for up to one year and any pre-approval is detailed as to the particular service or category of services and is generally subject to a specific budget. The independent auditors and management are required to periodically report to our Board of Directors regarding the extent of services provided by the independent auditors in accordance with this pre-approval, and the fees for the services performed to date. The Board of Directors may also pre-approve particular services on a case-by-case basis. Directors may also pre-approve particular services on a case-by-case basis.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on April 17, 2007.

IR BIOSCIENCES HOLDINGS, INC.

Date: April 17, 2007 By: /s/ Michael K. Wilhelm
Michael K. Wilhelm
President and Chief Executive Officer

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

SIGNATURE	TITLE	DATE
/s/ Michael K. Wilhelm Michael K. Wilhelm	Chief Executive Officer, President and Director (Principal Executive Officer)	April 17, 2007
/s/ John N. Fermanis John N. Fermanis	Chief Financial Officer (Principal Financial and Accounting Officer)	April 17, 2007
/s/ Theodore E. Staahl Theodore E. Staahl, M.D.	Director	April 17, 2007
/s/ Hal N. Siegel Hal N. Siegel, Ph.D.	Director	April 17, 2007