IR BIOSCIENCES HOLDINGS INC
Form 10KSB
March 31, 2008

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

FORM 10-KSB

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x	Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the fiscal year ended December 31, 2007
	OR
o	Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

COMMISSION FILE NUMBER: 33-05384

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

DELAWARE (State or Other Jurisdiction of Incorporation or Organization)	13-3301899 (I.R.S. Employer Identification No.)
8767 E. Via de Ventura, Suite 190, Scottsdale, AZ (Address of Principal Executive Offices)	85258 (Zip Code)

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

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

NONE

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

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

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

Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act of 1934 during the past 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No o

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. o

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

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

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

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

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

Transitional Small Business Disclosure Format Yes o No x

Table of Contents

TABLE OF CONTENTS

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 OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS" AND ELSEWHERE THROUGHOUT THIS ANNUAL REPORT. GIVEN THESE RISKS AND UNCERTAINTIES, YOU ARE CAUTIONED NOT TO PLACE UNDUE RELIANCE ON SUCH FORWARD-LOOKING STATEMENTS. THE FORWARD-LOOKING STATEMENTS INCLUDED IN THIS REPORT ARE MADE ONLY AS OF THE DATE HEREOF. WE DO NOT UNDERTAKE AND SPECIFICALLY DECLINE ANY OBLIGATION TO UPDATE ANY SUCH STATEMENTS OR TO PUBLICLY ANNOUNCE THE RESULTS OF ANY REVISIONS TO ANY OF SUCH STATEMENTS TO REFLECT FUTURE EVENTS OR DEVELOPMENTS. WHEN USED IN THE REPORT, UNLESS OTHERWISE INDICATED, "WE," "OUR," "US," THE "COMPANY" OR "IMMUNEREGEN" REFERS TO IR BIOSCIENCES HOLDINGS, INC. AND ITS SUBSIDIARY, IMMUNEREGEN BIOSCIENCES, INC.

Table of Contents

PART I

ITEM 1. DESCRIPTION OF BUSINESS

OVERVIEW

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

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

Our current focus is to develop Homspera for regenerating or strengthening the human immune system, in part, through stimulating human adult stem cells. It is the belief of our management, that the stem cell activity exhibited by Homspera underlies some of the effects previously reported in potential applications like treatment for radiation exposure and infectious disease using Homspera derivatives Radilex and Viprovex, respectively, which are described below. Recent studies have evaluated the effects of Homspera on human adult stem cell activity. Additionally, ongoing studies are being performed to evaluate the efficacy of Homspera as a potential product to increase the healing rate of wounds.

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

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

efficacy of Viprovex as a potential treatment for exposure to chemical agents, such as formalin.

To date we have submitted preliminary study data to the U.S. Food and Drug Administration (FDA) and have been issued two Pre-Investigational New Drug (PIND) numbers, one for the potential use of Radilex in the treatment of acute radiation syndrome and the other for the potential use of Viprovex in the treatment of avian influenza. We have contracted with an FDA regulatory consultant to assist us in our preparation and submission of an Investigational New Drug application (IND), a necessary prerequisite to human clinical studies, which can only follow after the FDA's allowance of our IND.

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

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

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

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

Table of Contents

SUBSTANCE P AND HOMSPERA™

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

Substance P

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

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

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

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

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

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

Homspera

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

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

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

Homspera, or Sar9, Met (O2)11-Substance P differs from Substance P in at least two ways. It is reported to be active at only the NK1 receptor, and to be more resistant to the enzymes that break down Substance P thereby terminating its action. Thus Sar9, Met (O2)11-Substance P is both more specific than Substance P, and also more persistent in the body.

Table of Contents

Applications

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

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

The initial pre-clinical applications we are researching include: (i) stem cell activity/immune system strengthening (Homspera); (ii) wound healing (Homspera); (iii) treating the effects on the body caused by exposure to radiation (Radilex); (iv) treating the effects on the body caused by infectious disease and harmful biological materials (Viprovex); (v) vaccine adjuvants (Viprovex); and, (vi) treating the effects on the body caused by exposure to harmful chemical agents (Viprovex). In addition to these six potential applications, we continue to explore the potential capabilities of Homspera and strive to better understand the mechanisms of this compound in order to further our development efforts with regard to not only our current application research, but also potential future applications.

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

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

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

Table of Contents

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

HOMSPERA™

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

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

Adult Stem Cells

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

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

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

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

We believe the results of previous influenza studies can be partly explained by Homspera's potential ability to enhance the immune system. In one study, Homspera treatment correlated with an increase in survival of animals infected

with influenza. Additionally, there were decreased levels of virus in both the lungs and nasal passage in animals treated with Homspera. We also see an increase in antibodies when Homspera is administered as a vaccine adjuvant to an influenza vaccine in small animals. These results suggest a possible role for Homspera in stimulating the immune system to increase the numbers of white blood cells, thereby preparing or helping the body to identify and target invading micro-organisms or foreign particles.

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

Wound Healing

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

Table of Contents

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

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

RADILEX®

All of our product candidates based on Radilex are in the pre-clinical stage of development. On January 14, 2004, we received a Pre-Investigational New Drug Application number for the use of Radilex (PIND No. 63,255) in the treatment of acute radiation syndrome. We believe the results of these and other studies suggest Radilex may play a role in increasing an individual's ability to overcome the effects of radiation, and, in the cases of exposure to potentially lethal radiation, to play a role in increased rates of survivability. Based on the sum of these studies, we believe that Radilex, once and if developed, could be an acceptable candidate to be purchased by governmental agencies for national distribution in the event of a significant nuclear or radiological threat. Further, we hope that a commercial market may develop for the potential use of Radilex as it relates to the treatment of radiation-induced side effects of cancer treatments, either as a stand-alone treatment or as a co-therapeutic agent to be used with other treatments.

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

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

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

believe that Homspera regenerates white blood cells in the circulation of animals exposed to radiation, and can play a pivotal role in the protective effect that we believe has been identified for Radilex.

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

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

VIPROVEX®

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

Table of Contents

Screening studies have been performed at the National Institutes of Health, National Institute of Allergy and Infectious Diseases