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IR BIOSCIENCES HOLDINGS INC  
Form 10KSB  
May 19, 2004

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, 2003.

OR

( ) 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

13-3301899

-----  
(State or Other Jurisdiction of  
Incorporation or Organization)

-----  
(I.R.S. Employer  
Identification No.)

8655 East Via De Ventura, Suite E-155

85258

-----  
(Address of Principal Executive Offices)

-----  
(Zip Code)

(480) 922-3926

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(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

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(Title of class)

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

No

X

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. [ X ]



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## SIGNATURES

### INTRODUCTORY NOTE

THE DISCUSSIONS IN THIS FORM 10-KSB MAY CONTAIN CERTAIN FORWARD-LOOKING STATEMENTS WITHIN THE MEANING OF SECTION 27A OF THE SECURITIES ACT OF 1933 AND SECTION 21E OF THE SECURITIES EXCHANGE ACT OF 1934. IN ADDITION, WHEN USED IN THIS FORM 10-KSB, THE WORDS "ANTICIPATES," "IN THE OPINION," "BELIEVES," "EXPECTS," AND SIMILAR EXPRESSIONS ARE INTENDED TO IDENTIFY FORWARD-LOOKING STATEMENTS. ACTUAL FUTURE RESULTS COULD DIFFER MATERIALLY FROM THOSE DESCRIBED IN THE FORWARD-LOOKING STATEMENTS AS A RESULT OF 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. THE COMPANY CAUTIONS THE READER, HOWEVER, THAT THIS LIST OF RISK FACTORS MAY NOT BE EXHAUSTIVE. THE COMPANY EXPRESSLY DISCLAIMS ANY OBLIGATION OR UNDERTAKING TO RELEASE PUBLICLY ANY UPDATES OR CHANGES TO THESE FORWARD-LOOKING STATEMENTS THAT MAY BE MADE TO REFLECT ANY ANTICIPATED OR UNANTICIPATED EVENTS OR CIRCUMSTANCES AFTER THE DATE OF SUCH STATEMENTS.

### PART I

#### ITEM 1. DESCRIPTION OF BUSINESS

Unless the context otherwise requires, references to "we," "us," the "Company" or "ImmuneRegen" mean IR BioSciences Holdings, Inc.

#### BUSINESS DEVELOPMENT

Our company, IR BioSciences Holdings, Inc., is a Delaware corporation and, until July 2001, was engaged in the business of assisting unaffiliated early-stage development and small to mid-sized emerging growth companies with financial and business development services, including raising capital in private and public offerings. During 2001, we failed to meet our revenue targets. On July 27, 2001, a majority interest in our company was acquired by a private investor, and we installed new management and adopted a new business plan. The immediate action taken regarding this new business plan was to discontinue our then current operations effective July 27, 2001.

On July 2, 2003, our company and ImmuneRegen Biosciences, Inc., a privately-held Delaware corporation ("ImmuneRegen"), entered into and consummated an Agreement and Plan of Merger (the "Merger"). In accordance with the Merger, on July 2, 2003, we acquired ImmuneRegen in exchange for 10,531,585 shares of our common stock. The transaction contemplated by the Agreement was intended to be a "tax-free" reorganization pursuant to the provisions of Section 351 and 368(a)(1)(A) of the Internal Revenue Code of 1986, as amended. On August 29, 2003, the Registrant's name was changed from GPN Network, Inc. to IR BioSciences Holdings, Inc.

#### CORPORATE STRUCTURE

IR BioSciences Holdings is a publicly-traded entity and has one wholly-owned subsidiary: ImmuneRegen BioSciences, Inc. ImmuneRegen BioSciences, Inc. is a Delaware Corporation, and was incorporated on October 30, 2002. Currently, all of our Company's operations are conducted by ImmuneRegen BioSciences, Inc.

#### BUSINESS DESCRIPTION

ImmuneRegen BioSciences, Inc. is a biotechnology company engaged in the research and development of applications utilizing modified substance P, a naturally

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occurring immunomodulator. Derived from homeostatic substance P, ImmuneRegen has named its proprietary compound "Homspera." Currently, ImmuneRegen holds two patents and four provisional patents in the United States. Additionally,

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ImmuneRegen holds a patent with the European Union and Australia and is seeking to extend its patents into Canada and, possibly, Japan.

ImmuneRegen's initial areas of focus will be in continuing development of several applications for use in improving pulmonary function and stimulating the immune system. These applications have been derived from research studies and positive results from laboratory tests conducted by management over the past nine years.

With the assistance of our U.S. Food and Drug Administration ("FDA") consultants, Synergos, Inc., ImmuneRegen plans to apply for Investigational New Drug ("IND") approval from the FDA. Based on ImmuneRegen's past test results and continuing studies, ImmuneRegen believes that its IND may be activated, allowing it to begin its human clinical trials using the Homspera compound as a treatment for lung injury caused by acute respiratory disease syndrome ("ARDS"), an often fatal disease.

ImmuneRegen's goal is to enter into overseas licensing and royalty agreements for its applications while awaiting approval by the FDA in the United States. Once approval has been obtained by the FDA, ImmuneRegen hopes to further expand its sales efforts internationally and will attempt to begin to generate sales domestically through the licensing and the direct sales of its products in the United States. A goal is to strategically align itself with larger pharmaceutical and other biotechnology and medical research companies, which ImmuneRegen believes may enhance its ability to succeed in reaching the objectives of bringing its applications to the marketplace. If FDA approval is granted, ImmuneRegen intends to seek to establish license agreements and relationships domestically that will bring Homspera to those in need of it.

### Substance P

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Substance P, first isolated in 1931, is a bioactive 11-amino acid peptide belonging to a group of neurokinins (small peptides that are broadly distributed in the central nervous system and peripheral nervous system). Substance P has been found to be involved in many physiological processes including pain modulation, smooth muscle contraction, blood pressure control, kidney function and water homeostasis. The peptide is widely distributed in numerous tissues and body fluids including the central and peripheral nervous system, gastrointestinal tract, visual system and circulatory system.

In the 1950s, substance P was considered to be the neurotransmitter for primary sensory afferent fibers, or the pain transmitter. By the 1970s, the biochemical properties of purified substance P were found to be a proteinaceous substance composed of amino acids that, subsequently, could be synthetically derived.

Since then, substance P has been extensively studied by researchers and scientists worldwide because of its many general physiological effects (smooth muscle contraction, inflammation, neurotransmission, blood vessel dilation, histamine release, and activation of the immune system) including its potential to stimulate epithelial growth; heal ulcers and ocular wounds; and, as a new approach to dulling anxiety and relieving depression and stress.

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ImmuneRegen's patents and continued substance P research are derived from discoveries made during research funded by the Air Force Office of Scientific Research in the early 1990s. During this research ImmuneRegen's founders, Drs. Witten and Harris, observed that the exposure of animals to jet fuels resulted in pathological changes in the lung and immune systems of those exposed. It was also observed that such exposure resulted in depletion of substance P from the lungs of the animals. These studies further showed that the administration of substance P may help prevent and reverse the effects of jet fuel exposure in the lungs, as well as protect and regenerate the immune system. The immune findings led to early research on the treatment of exposure to acute radiation and on the possible reversal of lung damage caused by ARDS and cigarette smoke.

### Research & Development

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Homspera is a proprietary compound created by modifying substance P. Based on initial findings and ongoing research studies, ImmuneRegen intends to initially focus on developing treatments for acute

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radiation syndrome ("ARS"), ARDS and hair replacement related to loss due to traditional anti-cancer treatments. Additionally, management believes that Homspera may be proven to provide applications for: 1) lessening lung damage caused by cigarette smoke and other toxicants related to air pollution; 2) the treatment of respiratory diseases associated with chronic obstructive pulmonary disease ("COPD"); 3) the treatment of lung and other cancers; 4) hair replacement; and, 5) the treatment of animals through the development of similar applications for use in veterinary medicine.

In the future, ImmuneRegen believes that it may be able to increase and strengthen its market position in the following ways: (i) working with the FDA to obtain the approval of the Homspera and future developments; (ii) investigating foreign markets for the use of Homspera and future products; and, (iii) continuing its current research into developing new applications.

ImmuneRegen has established a pilot manufacturing facility at its lab headquarters in Tucson, Arizona for the production of immune-based therapies. ImmuneRegen expect these facilities to be adequate to supply limited clinical trial quantities for its products under development. Additional manufacturing capacity will be needed for commercial scale production, if these therapies are approved for commercial sale.

For the manufacture of the applications under development, ImmuneRegen obtain synthetic peptides from third party manufacturers. ImmuneRegen believes that synthesized version of substance P is readily available at low cost from several life science and technology companies that provide biochemical and organic chemical products and kits used in scientific and genomic research, biotechnology, pharmaceutical development and the diagnosis of disease and chemical manufacturing. ImmuneRegen believes that the synthetic substance P and other materials necessary to produce Homspera are readily available from various sources, and several suppliers are capable of supplying substance P in both clinical and commercial quantities. These suppliers also store and ship the product as well.

ImmuneRegen expects that its products will use an inhaler (puffer) device to deliver Homspera to the user. To develop, manufacture and test an inhaler device ImmuneRegen hopes to partner with a drug development and chemical services company that offers services ranging from pre-clinical and toxicology studies to

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clinical trial support and manufacturing services. ImmuneRegen believes that such a partnership may enable it to decrease the time-to-market for its products and to increase its productivity.

### Our Products

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Based on its initial research findings, ImmuneRegen plans to initially develop applications using Homspera for:

- o The treatment for ARS;
- o The treatment of ARDS; and,
- o Hair loss replacement/attenuation due to its traditional anti-cancer treatments.

While performing the necessary research studies and due diligence to gain FDA approval of Homspera, ImmuneRegen hopes to enter into various license agreements, joint ventures and perform additional research overseas.

In conjunction with these initial areas ImmuneRegen plans to continue research and data collection, perform further research studies, and hopes to enter into license agreements overseas for:

- o Therapies that may lessen lung damage caused by cigarette smoke and other toxicants related to air pollution;
- o Providing a possible solution to the hair replacement industry; and,

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- o The treatment of animals through the possible development of similar applications for use in veterinary medicine.

Looking ahead, based on collected preliminary research data, ImmuneRegen believes it may be able to develop applications for:

- o Reducing the risk of cancer development;
- o Prevention of the spread and metastasis of cancer;
- o The treatment of lung and other cancers;
- o Enhancing an immune response to a viral infection; and,
- o Boosting a suppressed or failing immune system, which has direct applications in the treatment of the common cold, AIDS, food poisoning and slowing the effects of aging.

### Initial Applications

- o Immune-Based Therapies for Acute Radiation Sickness (ARS)

Radiation sickness, known as acute radiation sickness or syndrome, is a serious illness that occurs when the entire body (or most of it) receives a high dose of radiation, usually over a short period of time. The chance of survival for people with ARS decreases with increasing radiation dose. Most people who do not

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recover from ARS will die within several months of exposure. The cause of death in most cases is the destruction of the patient's bone marrow, which results in infections and internal bleeding. For the survivors, the recovery process may last from several weeks up to 2 years.

Radiation is a form of energy. It comes from man-made sources such as x-ray machines, from the sun and outer space, and from some radioactive materials such as uranium in soil. Small quantities of radioactive materials occur naturally in the air, the water, the food people eat, and in the human body. Radiation that goes inside the body causes what is referred to as internal exposure. The exposure that is referred to as external comes from sources outside the body, such as radiation from sunlight and man-made and naturally occurring radioactive materials. Radiation can affect the body in a number of ways, and the adverse health consequences of exposure may not be seen for many years. These effects can range from mild, such as skin reddening, to serious effects such as cancer and death, depending on the amount of radiation absorbed by the body (the dose), the type of radiation, the route of exposure, and the length of time a person is exposed. Exposure to very large doses of radiation may cause death within a few days or months. Exposure to lower doses of radiation may lead to an increased risk of developing cancer or other adverse health effects.

Because of recent terrorist events, people have expressed concern about the possibility of a terrorist attack involving radioactive materials, possibly through the use of a "dirty bomb," and the harmful effects of radiation from such an event. The adverse health consequences of a terrorist nuclear attack vary according to the type of attack and the distance a person is from the attack. Potential terrorist attacks may include a small radioactive source with a limited range of impact or a nuclear detonation involving a wide area of impact. In the event of a terrorist nuclear attack, people may experience two types of exposure from radioactive materials: external exposure and internal exposure. Exposure to very large doses of external radiation may cause death within a few days or months. External exposure to lower doses of radiation and internal exposure from breathing or eating radioactive contaminated material may lead to an increased risk of developing cancer and other adverse health effects. These adverse effects range from mild, such as skin reddening, to severe effects such as cancer and death, depending on the amount of radiation absorbed by the body (the dose), the type of radiation, the route of exposure, and the length of time of the exposure.

In animal studies, ImmuneRegen believes that it has achieved positive results using Homspera to treat animals subjected to varying levels of radioactive exposure. Although ImmuneRegen continues to perform

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studies in this area, it believes that Homspera may prove to be effective in the treatment of exposure to radiation.

Due to ImmuneRegen's relationship with the United States Government, if the results from additional studies are as expected, ImmuneRegen believes it may begin to realize revenue from the sale of Homspera within the next 12 months.

### o Immune-Based Therapies for Acute Respiratory Distress Syndrome

ImmuneRegen believes that little therapeutic progress has been achieved in the understanding of ARDS and the mortality remains high. ARDS is characterized as a severe injury to most or all of the lungs. Patients with ARDS experience severe shortness of breath and often require mechanical ventilation (life support) because of respiratory failure. ARDS is not a specific disease; instead, it is a

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type of severe, acute lung dysfunction that is associated with a variety of diseases, such as pneumonia, shock, sepsis (a severe infection in the body) and trauma. ARDS may be confused with congestive heart failure, which is another common condition that can also cause acute respiratory distress.

The majority of deaths in ARDS are due to nonrespiratory causes. Sepsis accounts for the majority of early deaths, and multiple organ failure is a prominent cause of late mortality. As there is no known cure, the current treatment is to identify and treat the underlying condition and keep the patient alive and breathing, usually requiring mechanical ventilation. With ARDS, the breathing muscles (i.e., the diaphragm and other muscles in the chest) become fatigued very quickly and can stop working in their effort to get oxygen into the body. The level of oxygen in the blood drops rapidly and to dangerously low levels, causing damage to vital organs and body processes. If the oxygen level is not brought up quickly and maintained at adequate levels, the damage, including severe brain damage, may be irreversible.

To date, there are no specific pharmacological interventions of proven value for the treatment of ARDS. However, based on positive results and exhaustive studies from treating lung damage due to jet fuel exposure, ImmuneRegen believes that its trials may prove Homspira could also be applicable with similar results to the treatment of ARDS.

### o Treatment for Hair Loss Related to Traditional Cancer Treatments

Although alopecia, (hair loss) is not life threatening, many cancer patients describe it as a traumatic side effect of chemotherapy, as well as a constant reminder of the cancer and its treatment. Patients experiencing hair loss encounter shedding of hair, obstacles to routine hair grooming, and difficulty in maintaining body heat, particularly at night, as well as scalp sensitivity and tenderness. Hair loss can also evoke feelings of low self-esteem and fear of how an altered appearance will be perceived by others.

Hair loss occurs because anticancer drugs can affect normal proliferating cells, including the cells responsible for hair growth. This effect, however, is not permanent, and healthy cells grow back normally once chemotherapy or radiation is completed. Scalp hairs in the, "anagen" or growing phase (about 90%) are susceptible to chemotherapy and radiation. The degree of hair loss depends on the chemotherapy drug, the dosage of chemotherapy or radiation, and how it is given.

In radiation treatments only hair that is in a treatment field will be affected with hair loss. Generally, the hair loss will begin approximately two to three weeks after the start of treatments. This hair will grow back after the treatments are completed. If a higher dose of radiation is delivered, there is a chance that the hair loss will be permanent.

Chemotherapy consists of the administration of drugs that destroy rapidly dividing cancer cells. Cancer cells are some of the most rapidly reproducing cells in the body, but other cells, such as those which contribute to the formation of hair shafts and nails, are also rapidly reproducing. Unfortunately, while chemotherapy drugs preferentially destroy cancer cells, the drugs also can destroy those cells responsible for normal growth of hair and nails. Cancer patients sometimes shed the hair and nails during treatment. Chemotherapy drugs are poisonous to the cells of the hair root responsible for hair shaft formation.



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Usually, the hair is lost rapidly in large quantities during treatment. In chemotherapy, hair loss starts approximately two to three weeks after the first dose of chemotherapy, but will not be noticeable until one to two months have elapsed. Hair loss is reversible and will be back totally about three to four months after the last chemotherapy dose.

ImmuneRegen believes that through research studies and experiments that aerosol treatments with Homspera may be proven to have the effect of replacing hair loss in animal models. Supporting its initial findings are studies by various research groups showing that substance P may be involved in hair modulation and has been shown in animal studies indicate to help induce the transition of hair from the telogen phase (final phase of the hair growth cycle where the hair falls out) to the anagen phase (first phase of the cycle where active hair growth occurs). Due to its initial findings and the existing outside research on substance P, ImmuneRegen believes that it may be able to develop applications using Homspera to treat the hair loss industry.

### Other Applications

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#### o Immune-Based Therapies for Cigarette Smoke and Other Toxicants

Air pollution is one of the most pervasive environmental problems because atmospheric currents can carry contaminated air to every part of the globe. Most air pollution comes from motor vehicle emissions and from power plants that burn coal and oil to produce energy for industrial and consumer use. Carbon dioxide and other harmful gases released into the air from these sources adversely affect weather patterns and the health of people. Fragile lung tissue is easily damaged by pollutants in the air, resulting in increased risk of asthma and allergies, chronic bronchitis, lung cancer and other respiratory diseases. Air pollution threatens the health of virtually every living being on the Earth. Studies have shown that indoor air quality is a significant concern as levels of many common pollutants have been shown to be 2 to 5 times higher, and occasionally more than 100 times higher indoors than they are outdoors.

ImmuneRegen believes that its results from treating lung damage due to jet fuel exposure may be proven to be applicable with similar results to damage caused to the lungs and air passages as a result of prolonged exposure to the harmful toxicants commonly found in polluted air and cigarette smoke. ImmuneRegen believes results from its preliminary studies that inhalation of Homspera may be proven to help prevent cellular and genetic damage due to cigarette smoke and preserve lung function. ImmuneRegen filed a provisional patent in August 2002 and expects to file a formal patent allotted under the provisional patent. ImmuneRegen hopes to seek foreign license agreements and strategic partners to begin the development and marketing of its product if the patent is granted.

#### o Immune-Based Therapies for the Veterinary Market

By developing therapies based on Homspera, ImmuneRegen seeks to be a developer and marketer of health products for the worldwide food animal and veterinary care markets. ImmuneRegen believes that the applications, which it is currently developing for human subjects and others specifically for animals, may be proven to be applicable to the numerous species of animals comprising the veterinary market. ImmuneRegen believes there may be potential applications in the food animal markets, including the dairy and beef cattle industries and the pork production industry, as well as large and small companion animal veterinary health care industries.

ImmuneRegen hopes that its Homspera-based products for veterinary applications may be offered initially in late 2003 to mid 2004, assuming the required regulatory approval is obtained. Further, the recent trend in the international drug industry, the merger of companies into larger and more competitive ones,

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reflects the highly competitive nature of the pharmaceutical industry. Currently, few domestic drug companies are competitive in the international animal drug market due to the lack of technology and marketing know-how including overseas drug registration procedures. ImmuneRegen believes that due to this trend and the lack of presence overseas, strategic partnerships and licenses may be available to it both domestically and internationally.

### Future Applications

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#### o Immune-Based Therapies for Cancer

Cancer remains the second-leading cause of death in the industrialized world and worldwide. As life expectancy continues to increase, so will cases of cancer. Products are beginning to emerge that are specifically targeted to cancer cells or act in collaboration with the body's immune response to combat the disease. ImmuneRegen believes that this marks a change in the way cancer is treated, and it believes that such innovative therapies may help transform the cancer market during the next decade.

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Based on results from initial research studies, ImmuneRegen believes that Homspera may be proven to help assist in the treatment of cancer. ImmuneRegen believes that Homspera may be proven to help the slowing and, possibly, preventing the spread and metastasis of cancer from the site of origin. Secondly, ImmuneRegen believes that Homspera may be proven to help boost the immune system, which may reduce the risks of cancer development and aids in recovery from chemotherapy and radiation treatments. Upon additional funding, ImmuneRegen expects to continue the development of Homspera for such applications.

#### o Immune-Based Therapies for the Common Cold/Flu

ImmuneRegen will also be focusing product development and discovery activities on viral respiratory infection ("VRI"), often referred to as the common cold. It has been estimated that adults suffer two to five colds per year, and infants and pre-school children have an average of four to eight colds per year. Due to its possible ability to help boost the immune system ImmuneRegen believes that Homspera may be proven to be an effective treatment in this application.

#### o Immune-Based Therapies for HIV/AIDS

AIDS, which is caused by the HIV virus, is a condition that slowly destroys the body's immune system making the body vulnerable to infections. HIV spreads through the body by invading host cells and using the host cells' protein synthesis capability to replicate. The immune system responds by producing antibody and cellular immune responses capable of attacking HIV. While these and other responses are usually sufficient to temporarily arrest progress of the infection and reduce levels of virus in the blood, the virus continues to replicate and slowly destroys the immune system by infecting and killing critical T cells, known as CD4 cells. As the infection progresses, the immune system's control of HIV weakens; the level of virus in the blood rises, and the level of T cells declines to a fraction of normal level. Currently available antiviral products have been shown to be effective at reducing the levels of virus in the blood; however, certain limitations in the therapy have prevented the antiviral products from being as effective as originally predicted. This is due primarily to HIV's ability to develop resistance to these drugs and the drugs' inability to stimulate the infected individual's own immune system to kill the virus.

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Based on initial research, ImmuneRegen believes that individuals treated with Homspera may be able to elicit immune responses to multiple subtypes of HIV. If proven, this type of broad cross reactivity may have future implications for both therapeutic and preventive vaccines. Based on initial research, ImmuneRegen believes that Homspera may be proven to boost HIV-specific immune responses and may induce a positive virologic effect in HIV-infected individuals. Based on initial research, ImmuneRegen believes Homspera may be proven to stimulate the production of specific antiviral substances that naturally protect components of the immune system from HIV infection. Furthermore, by utilizing an immune-based therapy such as Homspera, in conjunction with existing antiviral drugs, ImmuneRegen believes it may be possible to boost the HIV infected individual's immune system against the virus, such that the virologic effect of antiviral drug therapy is prolonged and enhanced.

### o Immune-Based Therapies for Food Poisoning

Food poisoning occurs worldwide, however it is most frequently reported in North America and Europe. Only a small proportion of infected people are tested and diagnosed.

Salmonella is responsible for a substantial portion of all cases of food poisoning and serious complications occur when the Salmonella bacteria make their way into the bloodstream.

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Once in the blood stream, the bacteria can enter any organ system throughout the body, causing disease. Other infections which may be caused by salmonella include:

- o Bone infections (osteomyelitis),
- o Joint infections (arthritis),
- o Infection of the sac containing the heart (pericarditis),
- o Infection of the tissues which cover the brain and spinal cord (meningitis),
- o Infection of the liver (hepatitis),
- o Lung infections (pneumonia),
- o Infection of aneurysms (aneurysms are abnormal outpouchings which occur in weak areas of the walls of blood vessels), and
- o Infections in the center of already-existing tumors or cysts.

Additionally, ImmuneRegen believes that Homspera may be proven to help prevent the spread of the salmonella bacteria, as well as other organisms that are a cause of food poisoning.

### Immuneregen's Strategy

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ImmuneRegen's strategy is to develop, test and obtain regulatory approval for various applications using Homspera in a diverse array of applications. The first two regulatory approvals ImmuneRegen hopes to obtain are in the United States and Europe. ImmuneRegen is currently investigating regulatory and other

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requirements in these countries, as well as others. ImmuneRegen is also evaluating other market for distribution of Homspera and hopes to secure potential strategic partners and licensees in these foreign markets.

ImmuneRegen's strategy is focused on the following major steps:

- o Establishing and formalizing strategic partnering relationships.

ImmuneRegen's aim is to establish relationships with industry leaders in the pharmaceutical and medical device industries for application-specific sales and distribution of its techniques and products, both domestic and international. ImmuneRegen believes this may have the effect of generating revenues in under twelve months after funding in the form of license agreements with companies in Europe and other countries, while awaiting possible FDA approval for sales in the United States to begin.

- o Accelerating current research efforts.

ImmuneRegen is working on capturing the full benefit of the Homspera technology in applications relating to the aforementioned fields. Further, the research that has produced Homspera could be applicable to other processes.

- o Expanding production facility capacity.

ImmuneRegen intends to operate a laboratory facility in Tucson, Arizona, which is equipped with state-of-the-art culture equipment, instrumentation and storage systems. ImmuneRegen intends to implement expansion plans if it receives its IND from the FDA.

- o Expanding sales, production and administrative resources.

Sales, increased research, and foreign affiliations will require more resources by ImmuneRegen. ImmuneRegen hopes these will be supplied through third party relationships and increases to staff as necessary.

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- o Supplementing and leveraging existing advisory relationships.

Pharmaceutical, biotechnology and corporate companies are a primary channel for introducing and distributing new products. To facilitate the marketing strategies outlined above, ImmuneRegen intends to supplement and leverage its existing relationships.

In the future, ImmuneRegen believes that it may be able to increase and strengthen its market position in the following ways: (i) working with the FDA to obtain the approval of the Homspera and future developments; (ii) investigating foreign markets for the use of Homspera and future products; and, (iii) continuing its current research into the science of attenuating ailments.

### Manufacturing

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ImmuneRegen has established a pilot manufacturing facility at its lab headquarters in Tucson, Arizona for the production of immune-based therapies. ImmuneRegen expects these facilities to be adequate to supply limited clinical trial quantities for our products under development. Additional manufacturing capacity will be needed for commercial scale production, if these therapies are approved for commercial sale.

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For the manufacture of the applications under development, ImmuneRegen obtains synthetic peptides from third party manufacturers. ImmuneRegen believes a synthesized version of substance P is readily available at low cost from several life science and technology companies that provide biochemical and organic chemical products and kits used in scientific and genomic research, biotechnology, pharmaceutical development and the diagnosis of disease and chemical manufacturing. ImmuneRegen believes that the synthetic substance P and other materials necessary to produce Homspira are readily available from various sources, and several suppliers are capable of supplying substance P in both clinical and commercial quantities. These suppliers also store and ship the product as well.

ImmuneRegen's products will use an inhaler (puffer) device to deliver Homspira to the user. To develop, manufacture and test an inhaler device, ImmuneRegen hopes to partner with a full-service drug development and chemical services company that offers services ranging from pre-clinical and toxicology studies to clinical trial support and manufacturing services. ImmuneRegen believes such a partnership may enable it to decrease the time-to-market for its products and to increase its productivity.

### Government Regulation

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Our development, manufacture and potential sale of therapeutics are subject to extensive regulation by United States and foreign governmental authorities. In particular, pharmaceutical products are subject to rigorous preclinical and clinical testing and to other approval requirements by the FDA in the United States under the Food, Drug and Cosmetic Act, and by comparable agencies in most foreign countries.

As an initial step in the FDA regulatory approval process, preclinical studies are typically conducted in animals to identify potential safety problems. For certain diseases, animal models exist that are believed to be predictive of human efficacy. For such diseases, a drug candidate is tested in an animal model. The results of the studies are submitted to the FDA as a part of the Investigational New Drug application (IND) that is filed to comply with FDA regulations prior to commencement of human clinical testing in the U.S. For diseases for which no appropriately predictive animal model exists, no such results can be filed. As a result, no IN VIVO evidence of efficacy would be available until such compounds progress to human clinical trials.

Clinical trials are typically conducted in three sequential phases, although the phases may overlap. In Phase I, which frequently begins with the initial introduction of the drug into healthy human subjects prior to introduction into patients, the compound will be tested for safety, dosage tolerance, absorption, bioavailability, biodistribution, metabolism, excretion, clinical pharmacology and, if possible, for early information on effectiveness. Phase II typically involves studies in a small sample of the intended patient population to assess the efficacy and duration of the drug for a specific indication, to determine dose tolerance and the optimal dose range and to gather additional information relating to safety and potential

adverse effects. Phase III trials are undertaken to further evaluate clinical safety and efficacy in an expanded patient population at geographically dispersed study sites, to determine the overall risk-benefit ratio of the drug and to provide an adequate basis for physician labeling. Each trial is conducted

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in accordance with certain standards under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Further, each clinical study must be evaluated by an independent Institutional Review Board at the institution at which the study will be conducted. The Institutional Review Board will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution.

Data from preclinical testing and clinical trials are submitted to the FDA in a New Drug Application (NDA) for marketing approval. The process of completing clinical testing and obtaining FDA approval for a new drug is likely to take a number of years and require the expenditure of substantial resources. Preparing an NDA involves considerable data collection, verification, analysis and expense, and there can be no assurance that approval will be granted on a timely basis, if at all. The approval process is affected by a number of factors, including the severity of the disease, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. The FDA may deny an NDA if applicable regulatory criteria are not satisfied or may require additional testing or information. Among the conditions for marketing approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to the FDA's CGMP regulations, which must be followed at all times. In complying with standards set forth in these regulations, manufacturers must continue to expend time, monies and effort in the area of production and quality control to ensure full mechanical compliance. Manufacturing establishments, both foreign and domestic, also are subject to inspections by or under the authority of the FDA and by or under the authority of other federal, state or local agencies.

Even after initial FDA approval has been obtained, further studies, including post-marketing studies, may be required to provide additional data on safety and will be required to gain approval for the use of a product as a treatment for clinical indications other than those for which the product was initially tested. Also, the FDA will require post-marketing reporting to monitor the side effects of the drug. Results of post-marketing programs may limit or expand further marketing of the drug products. Further, if there are any modifications to the drug, including changes in indication, manufacturing process, labeling or manufacturing facilities, an NDA supplement may be required to be submitted to the FDA.

The Orphan Drug Act provides incentives to drug manufacturers to develop and manufacture drugs for the treatment of diseases or conditions that affect fewer than 200,000 individuals in the United States. Orphan drug status can also be sought for diseases or conditions that affect more than 200,000 individuals in the United States if the sponsor does not realistically anticipate its product becoming profitable from sales in the United States. Under the Orphan Drug Act, a manufacturer of a designated orphan product can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for that product for the orphan indication. While the marketing exclusivity of an orphan drug would prevent other sponsors from obtaining approval of the same compound for the same indication, it would not prevent other types of drugs from being approved for the same use. We may apply for orphan drug status for the use of Homsperra for certain indications.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, a sponsor may be granted marketing exclusivity for a period of time following FDA approval of certain drug applications if FDA approval is received before the expiration of the patent's original term. This marketing exclusivity would prevent a third party from obtaining FDA approval for a similar or identical drug through an Abbreviated New Drug Application, which is the application form typically used by manufacturers seeking approval of a generic drug. The statute

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also allows a patent owner to extend the term of the patent for a period equal to one-half the period of time elapsed between the filing of an IND and the filing of the corresponding NDA plus the period of time between the filing of the NDA and FDA approval. We may seek the benefits of this statute, but there can be no assurance that we will be able to obtain any such benefits.

Whether or not FDA approval has been obtained, approval of a drug product by regulatory authorities in foreign countries must be obtained prior to the commencement of commercial sales of the product in such countries. Historically, the requirements governing the conduct of clinical trials and product approvals, and the time required for approval, have varied widely from country to country.

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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.

### FACILITIES

The Company has a lease agreement for 1,440 square feet of office space in Scottsdale, Arizona. The lease expires August 31, 2004. Rent expense is \$2,734 per month.

### EMPLOYEES

As of December 31, 2003, ImmuneRegen had one full-time employee and three contract employees. None of its employees are covered by a collective bargaining agreement.

### RISK FACTORS

The actual results of the combined company may differ materially from those anticipated in these forward-looking statements. The Registrant and ImmuneRegen will operate as a combined company in a market environment that is difficult to predict and that involves significant risks and uncertainties, many of which will be beyond the combined company's control. Additional risks and uncertainties not presently known, or that are not currently believed to be important to you, if they materialize, also may adversely affect the combined company.

IMMUNEREGEN HAS AN ACCUMULATED DEFICIT, IS NOT CURRENTLY PROFITABLE AND EXPECTS TO INCUR SIGNIFICANT EXPENSES IN THE NEAR FUTURE.

ImmuneRegen has incurred a substantial net loss for the period from its inception in October 2002 to June 30, 2003, and currently experiencing negative cash flow. ImmuneRegen expects to continue to experience negative cash flow and operating losses through at least 2004 and possibly thereafter. As a result, ImmuneRegen will need to generate significant revenues to achieve profitability. If ImmuneRegen's revenues grow more slowly than it anticipates, or if its operating expenses exceed its expectations, ImmuneRegen may experience reduced profitability.

IMMUNEREGEN'S INDEPENDENT OUTSIDE AUDITORS HAVE RAISED SUBSTANTIAL DOUBT ABOUT IMMUNEREGEN'S ABILITY TO CONTINUE AS A GOING CONCERN.

ImmuneRegen's independent certified public accountants have stated in their report included in this Form 10-KSB that the Company has incurred a net loss and

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negative cash flows from operations of \$1,856,702 and \$996,890, respectively, for the year ended December 31, 2003, and a lack of operational history, among other matters, that raise substantial doubt about its 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 ImmuneRegen's ability to raise capital, its relationship with potential suppliers and customers, and have other unforeseen effects.

THE REGISTRANT WILL BE REQUIRED TO RAISE ADDITIONAL CAPITAL TO FUND IMMUNEREGEN'S OPERATIONS. IF IMMUNEREGEN CANNOT RAISE NEEDED ADDITIONAL CAPITAL IN THE FUTURE, IT WILL BE REQUIRED TO CEASE OPERATIONS.

ImmuneRegen requires substantial working capital to fund its operations. Since it does not expect to generate significant revenues in the foreseeable future, in order to fund operations, ImmuneRegen will be completely dependent on additional debt and equity financing arrangements. There is no assurance that

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any financing will be sufficient to fund its capital expenditures, working capital and other cash requirements for the fiscal year ending December 31, 2004. No assurance can be given that any such additional funding will be available or that, if available, can be obtained on terms favorable to ImmuneRegen. If ImmuneRegen is unable to raise needed funds on acceptable terms, ImmuneRegen will not be able to develop or enhance its products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require the Registrant to take drastic steps such as reducing ImmuneRegen's level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, ImmuneRegen will not be able to continue operations.

IMMUNEREGEN'S LIMITED OPERATING HISTORY MAKES IT DIFFICULT TO EVALUATE THE SUCCESS OF ITS BUSINESS MODEL AND THE EFFECTIVENESS OF ITS MANAGEMENT. IF IMMUNEREGEN'S PLAN IS NOT SUCCESSFUL, OR MANAGEMENT IS NOT EFFECTIVE, THE VALUE OF THE REGISTRANT'S COMMON STOCK MAY DECLINE.

ImmuneRegen was founded in October 2002. As a result, ImmuneRegen has a limited operating history on which you can base your evaluation of its business and prospects. ImmuneRegen's business and prospects must be considered in light of the risks and uncertainties frequently encountered by companies in their early stages of development. These risks and uncertainties include the following:

- o ImmuneRegen's ability to raise additional funding and the amounts raised, if any;
- o The time and costs involved in obtaining regulatory approvals;
- o Continued scientific progress in ImmuneRegen's research and development programs;
- o The scope and results of preclinical studies and clinical trials;
- o The costs involved in filing, prosecuting and enforcing patent claims;
- o Competing technological and market developments;
- o Effective commercialization activities and arrangements;



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- o The costs of defending against and settling lawsuits; and
- o Other factors not within the combined company's control or known to it.

The combined company cannot be sure that it will be successful in meeting these challenges and addressing these risks and uncertainties. If it are unable to do so, ImmuneRegen's business will not be successful.

IMMUNEREGEN'S FAILURE TO SUCCESSFULLY DEVELOP AND COMMERCIALIZE PRODUCTS WILL CAUSE US TO CEASE OPERATIONS.

ImmuneRegen's failure to develop and commercialize products successfully will cause it to cease operations. Its potential therapies utilizing Homspera will require significant additional research and development efforts and regulatory approvals prior to potential commercialization in the future. ImmuneRegen cannot guarantee that it, or its corporate collaborators, if any, will ever obtain any regulatory approvals of Homspera. ImmuneRegen currently is focusing its core competencies on Homspera although there may be no assurance that it will be successful in so doing.

ImmuneRegen's therapies and technologies utilizing Homspera is at early stages of development and may not be shown to be safe or effective and may never receive regulatory approval. ImmuneRegen's technologies utilizing Homspera has not yet been tested in humans. Regulatory authorities may not permit human testing of potential products based on these technologies. Even if human testing is permitted, any potential products based on Homspera may not be successfully developed or shown to be safe or effective.

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The results of ImmuneRegen's preclinical studies and clinical trials may not be indicative or future clinical trial results. A commitment of substantial resources to conduct time-consuming research, preclinical studies and clinical trials will be required if it is to develop any products. Delays in planned patient enrollment in ImmuneRegen's clinical trials may result in increased costs, program delays or both. None of ImmuneRegen's potential products may prove to be safe or effective in clinical trials. Approval of the United States Food and Drug Administration, the FDA, or other regulatory approvals, including export license permissions, may not be obtained and even if successfully developed and approved, ImmuneRegen's potential products may not achieve market acceptance. Any products resulting from ImmuneRegen's 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 ImmuneRegen's proposed products. The appearance of any unacceptable toxicity or side effects could interrupt, limit, delay or abort the development of any of ImmuneRegen's proposed products or, if previously approved, necessitate their withdrawal from the market.

THE LENGTHY PRODUCT APPROVAL PROCESS AND UNCERTAINTY OF GOVERNMENT REGULATORY REQUIREMENTS MAY DELAY OR PREVENT IMMUNEREGEN FROM COMMERCIALIZING PROPOSED PRODUCTS.

Clinical testing, manufacture, promotion, export and sale of ImmuneRegen's proposed products are subject to extensive regulation by numerous governmental authorities in the United States, principally the FDA, and corresponding state

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and foreign regulatory agencies. This regulation may delay or prevent ImmuneRegen from commercializing proposed products. Noncompliance with applicable requirements can result in, among other things, fines, injunctions, seizure or recall of such products, total or partial suspension of product manufacturing and marketing, failure of the government to grant premarket approval, withdrawal of marketing approvals and criminal prosecution.

The regulatory process for new therapeutic drug products, including the required preclinical studies and clinical testing, is lengthy and expensive. ImmuneRegen may not receive necessary FDA clearances for any of its potential products in a timely manner, or at all. The length of the clinical trial process and the number of patients the FDA will require to be enrolled in the clinical trials in order to establish the safety and efficacy of ImmuneRegen's proposed products is uncertain.

Even if human clinical trials of Homspera are initiated and successfully completed, the FDA may not approve Homspera for commercial sale. ImmuneRegen may encounter significant delays or excessive costs in its 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. ImmuneRegen may not be able to obtain the necessary approvals for clinical trials, manufacturing or marketing of any of our 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.

In addition, a marketed product is subject to continual FDA review. Later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market, as well as possible civil or criminal sanctions.

Among the other requirements for regulatory approval is the requirement that prospective manufacturers conform to the FDA's Good Manufacturing Practices, or GMP, requirements. In complying with the FDA's GMP requirements, manufacturers must continue to expend time, money and effort in production, record keeping and quality control to assure that products meet applicable specifications and other requirements. Failure to comply and maintain compliance with the FDA's GMP requirements subjects manufacturers to possible FDA regulatory action and as a result, may have a material adverse effect on ImmuneRegen. ImmuneRegen, or its contract manufacturers, if any, may not be able to maintain compliance with the

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FDA's GMP requirements on a continuing basis. Failure to maintain compliance could have a material adverse effect on ImmuneRegen.

The FDA has not designated expanded access protocols for Homspera as "treatment" protocols. The FDA may not determine that Homspera meets all of the FDA's criteria for use of an investigational drug for treatment use. Even if Homspera is allowed for treatment use, third party payers may not provide reimbursement for the costs of treatment with Homspera. The FDA also may not consider Homspera to be an appropriate candidate for accelerated approval, expedited review or fast track designation.

Marketing any drug products outside of the United States will subject ImmuneRegen to numerous and varying foreign regulatory requirements governing the design and conduct of human clinical trials and marketing approval. Additionally, ImmuneRegen's ability to export drug candidates outside the United

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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.

TECHNOLOGICAL CHANGE AND COMPETITION MAY RENDER IMMUNEREGEN'S POTENTIAL PRODUCTS OBSOLETE.

The life science industry continues to undergo rapid change, and competition is intense and is expected to increase. Competitors may succeed in developing technologies and products that are more effective or affordable than any that ImmuneRegen is developing or that would render ImmuneRegen's technology and proposed products obsolete or noncompetitive. Most of ImmuneRegen's competitors have substantially greater experience, financial and technical resources and production, marketing and development capabilities. Accordingly, some of ImmuneRegen's competitors may succeed in obtaining regulatory approval for products more rapidly or effectively than it, or technologies and products that are more effective and affordable than any that ImmuneRegen is currently developing.

IMMUNEREGEN'S LACK OF COMMERCIAL MANUFACTURING AND MARKETING EXPERIENCE MAY PREVENT IT FROM SUCCESSFULLY COMMERCIALIZING PRODUCTS.

ImmuneRegen has not manufactured any of its products in commercial quantities. ImmuneRegen may not successfully make the transition from manufacturing clinical trial quantities to commercial production quantities or be able to arrange for contract manufacturing and this could prevent us from commercializing products or limit our profitability from our products. Even if Homspera is successfully developed and receives FDA approval, ImmuneRegen has not demonstrated the capability to manufacture Homspera in commercial quantities. ImmuneRegen has not demonstrated the ability to manufacture Homspera in large-scale clinical quantities. ImmuneRegen expects to rely on third parties for the final activation step of the Homspera manufacturing process. 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 ImmuneRegen could establish other manufacturing capacity on a timely basis.

IMMUNEREGEN HAS NO EXPERIENCE IN THE SALES, MARKETING AND DISTRIBUTION OF PHARMACEUTICAL OR BIOTECHNOLOGY PRODUCTS. THUS, IMMUNEREGEN'S PROPOSED PRODUCTS MAY NOT BE SUCCESSFULLY COMMERCIALIZED EVEN IF THEY ARE DEVELOPED AND APPROVED FOR COMMERCIALIZATION.

The manufacturing process of ImmuneRegen's proposed products is expected to involve a number of steps and requires compliance with stringent quality control specifications imposed by ImmuneRegen and by the FDA. Moreover, it is expected that ImmuneRegen's proposed products may be manufactured only in a facility that has undergone a satisfactory inspection and certification by the FDA. For these reasons, ImmuneRegen would not be able to quickly replace its manufacturing capacity if we were unable to use its manufacturing facilities as a result of a fire, natural disaster (including an earthquake), equipment failure or other difficulty, or if such facilities are deemed not in compliance with the GMP requirements, and the noncompliance could not be rapidly rectified. ImmuneRegen's inability or reduced capacity to

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manufacture its proposed products would prevent it from successfully commercializing its proposed products.

ImmuneRegen may enter into arrangements with contract manufacturing companies in order to meet requirements for its products, or to attempt to improve manufacturing efficiency. If ImmuneRegen chooses to contract for manufacturing services, ImmuneRegen may encounter costs, delays and/or other difficulties in producing, packaging and distributing its clinical trials and finished product. Further, contract manufacturers must also operate in compliance with the GMP requirements; failure to do so could result in, among other things, the disruption of its product supplies. ImmuneRegen's potential dependence upon third parties for the manufacture of its proposed products may adversely affect its profit margins and its ability to develop and deliver proposed products on a timely and competitive basis.

ADVERSE DETERMINATIONS CONCERNING PRODUCT PRICING, REIMBURSEMENT AND RELATED MATTERS COULD PREVENT IMMUNEREGEN FROM SUCCESSFULLY COMMERCIALIZING HOMSPERA.

ImmuneRegen's ability to earn sufficient revenue on Homspera or any other proposed products 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 it from successfully commercializing Homspera or any proposed products. Third-party payers are increasingly challenging the prices of medical products and services. If purchasers or users of Homspera or any such other proposed products 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.

IMMUNEREGEN'S SUCCESS WILL DEPEND UPON THE ACCEPTANCE OF HOMSPERA BY THE MEDICAL COMMUNITY.

ImmuneRegen's ability to market and commercialize Homspera depends on the acceptance and utilization of Homspera by the medical community. ImmuneRegen will need to develop commercialization initiatives designed to increase awareness about it and Homspera among targeted audiences, including public health activists and community-based outreach groups in addition to the investment community. Currently, ImmuneRegen has not developed any such initiatives. Without such acceptance of Homspera, the product upon which ImmuneRegen expects to be substantially dependent, ImmuneRegen may not be able to successfully commercialize Homspera or generate revenue.

PRODUCT LIABILITY EXPOSURE MAY EXPOSE IMMUNEREGEN TO SIGNIFICANT LIABILITY.

ImmuneRegen faces an inherent business risk of exposure to product liability and other claims and lawsuits in the event that the development or use of its technology or prospective products is alleged to have resulted in adverse effects. ImmuneRegen may not be able to avoid significant liability exposure. ImmuneRegen may not have sufficient insurance coverage, and ImmuneRegen 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 its products. A product liability claim could hurt its financial performance. Even if ImmuneRegen avoids liability exposure, significant costs could be incurred that could hurt its financial performance.

IF IMMUNEREGEN FAILS TO ATTRACT AND RETAIN CONSULTANTS AND EMPLOYEES, ITS GROWTH COULD BE LIMITED AND ITS COSTS COULD INCREASE, WHICH MAY ADVERSELY AFFECT ITS RESULTS OF OPERATIONS AND FINANCIAL POSITION.

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ImmuneRegen's future success depends in large part upon its ability to attract and retain highly skilled executive-level management and scientific personnel. The competition in the scientific industry for such personnel is intense, and ImmuneRegen cannot be sure that it will be successful in attracting and retaining such personnel. Most of ImmuneRegen's consultants and employees and several of its executive officers began working for ImmuneRegen recently, and all employees are subject to "at will"

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employment. Most of ImmuneRegen's consultants and employees are not subject to non-competition agreements. ImmuneRegen cannot guarantee that it will be able to replace any of its management personnel in the event their services become unavailable.

IMMUNEREGEN'S PATENTS AND PROPRIETARY TECHNOLOGY MAY NOT BE ENFORCEABLE AND THE PATENTS AND PROPRIETARY TECHNOLOGY OF OTHERS MAY PREVENT IMMUNEREGEN FROM COMMERCIALIZING PRODUCTS.

Although ImmuneRegen believes its patents to be protected and enforceable, the failure to obtain meaningful patent protection products and processes would greatly diminish the value of its potential products and processes.

In addition, whether or not ImmuneRegen's patents are issued, or issued with limited coverage, others may receive patents, which contain claims applicable to its products. Patents we are not aware of may adversely affect ImmuneRegen's ability to develop and commercialize 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. ImmuneRegen also relies upon non-patented trade secrets and know how, and others may independently develop substantially equivalent trade secrets or know how. ImmuneRegen also relies on protecting our proprietary technology in part through confidentiality agreements with its current and former corporate collaborators, employees, consultants and certain contractors. These agreements may be breached, and ImmuneRegen may not have adequate remedies for any such breaches. In addition, ImmuneRegen's trade secrets may otherwise become known or independently discovered by ImmuneRegen's competitors. Litigation may be necessary to defend against claims of infringement, to enforce ImmuneRegen's 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 ImmuneRegen to significant liabilities to third parties, require disputed rights to be licensed or require ImmuneRegen to cease using certain technologies.

IMMUNEREGEN'S PRODUCTS AND SERVICES COULD INFRINGE ON THE INTELLECTUAL PROPERTY RIGHTS OF OTHERS, WHICH MAY CAUSE IT TO ENGAGE IN COSTLY LITIGATION AND, IF IS NOT SUCCESSFUL, COULD CAUSE IT TO PAY SUBSTANTIAL DAMAGES AND PROHIBIT IT FROM SELLING OUR PRODUCTS OR SERVICING IMMUNEREGEN'S CLIENTS.

ImmuneRegen cannot be certain that its technology and other intellectual property does not infringe upon the intellectual property rights of others. Authorship and priority of intellectual property rights may be difficult to verify. Because patent applications in the United States are not publicly disclosed until the patent is issued, applications may have been filed which relate to services similar to those offered by ImmuneRegen. ImmuneRegen may be subject to legal proceedings and claims from time to time in the ordinary course

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of its business, including claims of alleged infringement of the trademarks and other intellectual property rights of third parties.

If ImmuneRegen's products violate third-party proprietary rights, it cannot assure you that it 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 it from providing services. Such claims could severely harm ImmuneRegen's financial condition and ability to compete.

HAZARDOUS MATERIALS AND ENVIRONMENTAL MATTERS COULD EXPOSE IMMUNEREGEN TO SIGNIFICANT COSTS.

ImmuneRegen may be required to incur significant costs to comply with current or future environmental laws and regulations. Although ImmuneRegen does not currently manufacture commercial quantities of its proposed products, it does produce limited quantities of these products for its clinical trials. ImmuneRegen's research and development and manufacturing processes involve the controlled storage,

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use and disposal of hazardous materials, biological hazardous materials and radioactive compounds. ImmuneRegen is 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 ImmuneRegen believes that its 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, ImmuneRegen 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 ImmuneRegen's operations, business and assets.

Risks Related to Capital Structure

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IMMUNEREGEN'S STOCK PRICE IS VOLATILE AND COULD DECLINE IN THE FUTURE.

The price of ImmuneRegen's common stock has been volatile in the past and will likely continue to fluctuate in the future. The stock market in general and the market for shares of life science companies in particular have experienced extreme stock price fluctuations. In some cases, these fluctuations have been unrelated to the operating performance of the affected companies. Many companies in the life science and related industries have experienced dramatic volatility in the market prices of their common stock. The Registrant believes that a number of factors, both within and outside our control, could cause the price of the Registrant's common stock to fluctuate, perhaps substantially. Factors such as the following could have a significant adverse impact on the market price of the ImmuneRegen's common stock:

- o The Registrant's ability to obtain additional financing and, if available, the terms and conditions of the financing;
- o ImmuneRegen's financial position and results of operations;
- o The results of preclinical studies and clinical trials by ImmuneRegen, its collaborators or its competitors;

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- o Concern as to, or other evidence of, the safety or efficacy of ImmuneRegen's proposed products or its competitors' products;
- o Announcements of technological innovations or new products by ImmuneRegen or its competitors;
- o U.S. and foreign governmental regulatory actions;
- o Actual or anticipated changes in drug reimbursement policies;
- o Developments with ImmuneRegen's collaborators, if any;
- o Developments concerning patent or other proprietary rights of ImmuneRegen or its competitors (including litigation);
- o Status of litigation;
- o Period-to-period fluctuations in ImmuneRegen's operating results;
- o Changes in estimates of the combined company's performance by any securities analysts;
- o New regulatory requirements and changes in the existing regulatory environment;
- o Market conditions for life science stocks in general.

THERE IS NO ASSURANCE OF AN ESTABLISHED PUBLIC TRADING MARKET.

Although ImmuneRegen's common stock trades on the NASD OTC Bulletin Board, a regular trading market for the securities may not be sustained in the future. The NASD has enacted recent changes that

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limit quotations on the OTC Bulletin Board to securities of issuers that are current in their reports filed with the Securities and Exchange Commission. The effect on the OTC Bulletin Board of these rule changes and other proposed changes cannot be determined at this time. The OTC Bulletin Board is an inter-dealer, Over-The-Counter market that provides significantly less liquidity than the NASD's automated quotation system (the "NASDAQ Stock Market"). Quotes for stocks included on the OTC Bulletin Board are not listed in the financial sections of newspapers as are those for the NASDAQ Stock Market. Therefore, prices for securities traded solely on the OTC Bulletin Board 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. Market prices for ImmuneRegen's common stock will be influenced by a number of factors, including:

- o the issuance of new equity securities pursuant to a future offering;
- o changes in interest rates;
- o competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- o variations in quarterly operating results;

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- o change in financial estimates by securities analysts;
- o the depth and liquidity of the market for ImmuneRegen's common stock;
- o investor perceptions of our company and the technologies industries generally; and
- o general economic and other national conditions.

IMMUNEREGEN'S COMMON STOCK IS CONSIDERED A "PENNY STOCK."

ImmuneRegen's common stock is considered to be a "penny stock" since it meets one or more of the definitions in Rules 15g-2 through 15g-6 promulgated under Section 15(g) of the Securities Exchange Act of 1934, as amended. These include but are not limited to the following: (i) the stock trades at a price less than five dollars (\$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 five dollars (5.00) per share; or (iv) is issued by a company with net tangible assets less than \$2,000,000, if in business more than a continuous three years, or with average revenues of less than \$6,000,000 for the past three years. The principal result or effect of being designated a "penny stock" is that securities broker-dealers cannot recommend the stock but must trade in it on an unsolicited basis.

BROKER-DEALER REQUIREMENTS MAY AFFECT TRADING AND LIQUIDITY.

Section 15(g) of the Securities Exchange Act of 1934, as amended, and Rule 15g-2 promulgated thereunder by the SEC require 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 before effecting any transaction in a penny stock for the investor's account.

Potential investors in ImmuneRegen's common stock are urged to obtain and read such disclosure carefully before purchasing any shares that are deemed to be "penny stock." 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

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with these requirements may make it more difficult for holders of ImmuneRegen's common stock to resell their shares to third parties or to otherwise dispose of them in the market or otherwise.

IMMUNEREGEN'S EXECUTIVE OFFICERS, DIRECTORS AND PRINCIPAL STOCKHOLDERS CONTROL OUR BUSINESS AND MAY MAKE DECISIONS THAT ARE NOT IN OUR BEST INTERESTS.

ImmuneRegen's officers, directors and principal stockholders, and their affiliates, in the aggregate, own over a majority of the outstanding shares of



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our common stock. As a result, such persons, acting together, have the ability to substantially influence all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets, and to control ImmuneRegen's management and affairs. Accordingly, such concentration of ownership may have the effect of delaying, deferring or preventing a change in discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of ImmuneRegen's business, even if such a transaction would be beneficial to other stockholders.

SALES OF ADDITIONAL EQUITY SECURITIES MAY ADVERSELY AFFECT THE MARKET PRICE OF OUR COMMON STOCK AND YOUR RIGHTS IN THE REGISTRANT MAY BE REDUCED.

Certain of ImmuneRegen's stockholders have the right to hold securities registered pursuant to registration rights agreements. The sale or the proposed sale of substantial amounts of ImmuneRegen's equity securities or convertible debt securities may adversely affect the market price of its common stock and its stockholders may experience substantial dilution. Also, any new equity securities issued may have greater rights, preferences or privileges than ImmuneRegen's existing common stock.

IMMUNEREGEN CAN ISSUE SHARES OF PREFERRED STOCK WITH RIGHTS SUPERIOR TO THOSE OF THE HOLDERS OF OUR COMMON STOCK. SUCH ISSUANCES CAN DILUTE THE TANGIBLE NET BOOK VALUE OF SHARES OF THE REGISTRANT'S COMMON STOCK.

ImmuneRegen's Board of Directors is authorized to issue up to 10,000,000 shares of blank check preferred stock with rights that are superior to the rights of the stockholders of its common stock, at a purchase price substantially lower than the market price of shares of its common stock without stockholder approval.

WE HAVE NO INTENTION TO PAY DIVIDENDS.

ImmuneRegen has never declared or paid any dividends on its securities. ImmuneRegen currently intends to retain its earnings for funding growth and, therefore, does not expect to pay any dividends in the foreseeable future.

### ITEM 2. DESCRIPTION OF PROPERTY

The Company has a lease agreement for 1,440 square feet of office space in Scottsdale, Arizona. The lease expires August 31, 2004. Rent expense is \$2,734 per month. ImmuneRegen subleases its office space from Foresight Capital Partners, a company controlled by ImmuneRegen's CEO. The rent cost is passed through to ImmuneRegen at the same rental rate that Foresight Capital Partners is charged by the facility's primary landlord.

### ITEM 3. LEGAL PROCEEDINGS

On December 13, 2001, service of process was effectuated upon GPN with regard to a fee agreement between GPN and Silver and Deboskey, a Professional Corporation located in Denver, Colorado. On November 27, 2002, judgment was entered in favor of Silver & Deboskey in the amount of \$28,091. At December 31, 2003, the Company has not paid any of this amount.

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

None.

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## PART II

### ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

The Company's common stock is approved for quotation on the NASD OTC Bulletin Board under the symbol "IRBO". From July 2, 2003 through April 6, 2004, the ImmuneRegen traded under the symbol "IRBH". Previous to July 2, 2003, the Company traded under the symbol "GPNN". The following table sets forth the high and low bid prices for the Company's 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.

	2003	
	HIGH	LOW
-----	-----	-----
1st Quarter	\$0.20	\$0.20
2nd Quarter	4.00	0.20
3rd Quarter	9.00	1.10
4th Quarter	2.25	0.55
-----	-----	-----
	2001	
	HIGH	LOW
-----	-----	-----
1st Quarter	\$0.80	\$0.40
2nd Quarter	0.40	0.30
3rd Quarter	0.70	0.20
4th Quarter	0.40	0.10
-----	-----	-----

At May 5, 2004, there were approximately 374 holders of record of the Company's Common Stock.

The Company has not paid any dividends on its shares of common stock since its inception and does not anticipate that dividends will be paid in the immediate future.

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

The following information should be read in conjunction with the financial statements and the notes thereto. 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 FORM 10-KSB 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," "WILL," "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

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DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS SET FORTH BELOW, AS WELL AS IN "RISK FACTORS" SET FORTH HEREIN. GPN NETWORK UNDERTAKES NO OBLIGATION TO UPDATE ANY FORWARD-LOOKING STATEMENT, WHETHER AS A RESULT OF NEW INFORMATION, FUTURE EVENTS OR OTHERWISE. READERS SHOULD CAREFULLY REVIEW THE FACTORS SET FORTH IN OTHER REPORTS OR DOCUMENTS THAT GPN NETWORK FILES FROM TIME-TO-TIME WITH THE SEC.

### Overview

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ImmuneRegen BioSciences, Inc. is development stage biotechnology company engaged in the research and development of applications utilizing modified substance P, a naturally occurring immunomodulator. Derived from homeostatic substance P, ImmuneRegen has named its proprietary compound "Homspera." Currently, ImmuneRegen holds two patents and four provisional patents in the United States. Additionally, ImmuneRegen holds a patent with the European Union and Australia and is seeking to extend its patents into Canada and, possibly, Japan.

ImmuneRegen's initial areas of focus will be in continuing development of several applications for use in improving pulmonary function and stimulating the immune system. These applications have been derived from research studies and positive results from laboratory tests conducted by management over the past nine years.

### LIQUIDITY AND CAPITAL RESOURCES

From the date of inception (October 30, 2002) through December 31, 2003, the Company has raised \$951,000 from the issuance of notes payable (net of repayments of \$250,000) and \$96,001 from the sale of common stock. Cash used by operating activities from the date of inception (October 30, 2002) through December 31, 2003 was \$1,033,163, and cash used in investing activities was \$3,304.

At December 31, 2003, the Company had negative working capital of \$866,040. This amount consisted primarily of cash of \$10,534 and prepaid services and other current assets of \$35,843, and current liabilities of accounts payable and accrued liabilities of \$413,441, accrued consulting fees of \$125,000, and notes payable plus convertible notes payable (net of discount) of \$62,171 and \$311,805, respectively. The actual cash amount due on the notes payable without considering the discount is an additional \$339,195, or \$713,171. The gross amount of liabilities coming due within twelve months at December 31, 2003 is \$1,252,359.

At December 31, 2003, the Company had in place a total of seventeen notes payable for a gross amount due of \$713,171 less discounts of \$339,195 relating to warrants issued with the notes. These notes mature at various dates from January through June 2004. At May 5, 2004, thirteen of these notes in the aggregate amount of \$575,000 were in default as they have not been repaid within their stated term. During May 2004, the Company executed 90 day extensions to the terms of these notes.

Thirteen of these notes in the aggregate amount of \$566,000 will automatically convert to common stock should the Company raise at least \$500,000 in proceeds from investors (the "Qualified Financing"). At May 5, 2004, the Company had underway a private placement of its common stock (the "Private Placement") by which the Company intends to raise approximately \$1,500,000, though there can be absolutely no assurance that this or any amount will actually be raised. Should the Private Placement result in raising at least \$500,000, it will become a Qualified Financing and the thirteen convertible notes subject to automatic conversion provisions, plus accrued interest, will convert to equity.

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Even if the Company achieves a Qualified Financing, further capital infusions will be required in order to execute our business plan. The Company's independent certified public accountants have stated in their report, included in this Form 10-KSB, that the Company has incurred a net loss and negative cash flows from operations of \$1,856,702 and \$996,890, respectively, for the year ended December 31, 2003. This loss, in addition to a lack of operational history, raises a substantial doubt about its ability to continue as a going concern. In the absence of significant revenue and profits, and since it

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does not expect to generate significant revenues in the foreseeable future, the Company, in order to fund operations, will be completely dependent on additional debt and equity financing arrangements. There is no assurance that any financing will be sufficient to fund its capital expenditures, working capital and other cash requirements for the fiscal year ending December 31, 2004. No assurance can be given that any such additional funding will be available or that, if available, can be obtained on terms favorable to ImmuneRegen. If ImmuneRegen is unable to raise needed funds on acceptable terms, ImmuneRegen will not be able to develop or enhance its products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require the Registrant to take drastic steps such as reducing ImmuneRegen's level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, ImmuneRegen will not be able to continue operations.

On March 31, 2004, the Financial Accounting Standards Board (FASB) issued a proposed Statement, Share-Based Payment, an amendment of FASB Statements No. 123 and 95, that would require companies to account for stock-based compensation to employees using a fair value method as of the grant date. The proposed statement addresses the accounting for transactions in which a company receives employee services in exchange for equity instruments such as stock options, or liabilities that are based on the fair value of the company's equity instruments or that may be settled through the issuance of such equity instruments, which includes the accounting for employee stock purchase plans. This proposed statement would eliminate a company's ability to account for share-based awards to employees using APB Opinion 25, Accounting for Stock Issued to Employees but would not change the accounting for transactions in which a company issues equity instruments for services to non-employees or the accounting for employee stock ownership plans. The proposed statement, if adopted, would be effective for awards that are granted, modified, or settled in fiscal years beginning after December 15, 2004. The Company is in the process of assessing the potential impact of this proposed statement to the financial statements.

RESULTS OF OPERATIONS FOR THE TWELVE MONTH PERIOD ENDED DECEMBER 31, 2003 AND FOR THE PERIOD OF INCEPTION (OCTOBER 30, 2002) TO DECEMBER 31, 2003.

Revenue  
-----

The Company is currently in the development stage and has not yet generated any revenue.

Selling, General, and Administrative Expenses  
-----

During the twelve months ended December 31, 2003, selling, general, and administrative expenses ("SG&A") were \$1,348,078. This amount consists primarily of amortization of discount on notes payable of \$302,302, legal and accounting

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fees of \$259,381, consulting fees of \$197,741, officer salary of \$125,000, public relations and marketing of \$95,132, non-cash compensation of \$85,861, contract labor of \$46,454, research and development of \$42,972, and rent expense of \$31,369.

Total SG&A for the period of inception (October 30, 2002) through December 31, 2003, were \$1,393,796. This increase of \$45,718 from the twelve months ended December 31, 2003 consists primarily of an additional \$22,427 in public relations and website expenses, an additional \$12,986 in legal and accounting fees, and an additional \$6,613 in consulting fees.

Over the coming twelve months, the Company expects legal and accounting fees to remain high due to the compliance requirements of the Company's publicly-traded status. In addition, we intend to investigate possible acquisitions and strategic alliance arrangements which will require legal and accounting due diligence. Officer salary will increase during the coming twelve months to approximately \$175,000 pursuant to contractual arrangements. Public relations and marketing expenditures are expected to increase as we gain an understanding of the eventual placement of our products in the market. Contract labor expenditures are expected to increase over the coming twelve months as our overhead and administrative burden increases. Research and development will also increase as we further focus on

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developing our products for the marketplace. Rent expense is expected to stay constant for the coming twelve months.

### Merger Fees and Costs

-----

Merger fees and costs were \$350,000 for the twelve months end December 31, 2003 and for the period of inception (October 30, 2003) to December 31, 2003. This amount is related to the Merger which was consummated in July, 2003. \$185,000 of this amount was the cost of the merger shell, GPN Network, Inc. The remaining \$165,000 of these funds were used to satisfy certain outstanding liabilities of GPN.

During the twelve months ending December 31, 2004, the Company may investigate potential acquisition candidates, and the potential cash costs of such an acquisition or acquisitions is not possible to forecast.

### Financing Cost

-----

Financing costs were \$90,000 for the twelve months ending December 31, 2003 and for the period of inception (October 30, 2003) to December 31, 2003. This amount consists of non-refundable prepaid travel and road show costs.

The Company expects this amount to decrease in the twelve months ending December 31, 2004.

### Interest Expense

-----

Interest expense during the twelve months ended December 31, 2003 was \$68,624. This amount consists of interest payable on the Company's notes payable. An additional \$200 of interest was accrued during the period of inception (October 30, 2002) through December, 2002.

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If the Company achieves a Qualified Financing, it is anticipated that approximately \$566,000 of the \$713,171 notes payable outstanding will convert to equity, and that interest expense will subsequently be reduced during the twelve months ending December 31, 2004. There can be no guarantee, however, that this will be the case.

Net Loss

-----

For the reasons stated above, the Company's net loss for the twelve months ending December 31, 2003 was \$1,856,702 or \$0.17 per shares. For the period of inception (October 30, 2002) through December 31, 2003, the Company's net loss was \$1,902,620 or \$0.20 per share. The Company expects that losses will continue through the period ending December 31, 2004.

The Company's independent certified public accountants have stated in their report included in this Form 10-KSB that the Company has incurred a net loss and negative cash flows from operations of \$1,856,702 and \$996,890, respectively, for the year ended December 31, 2003. This loss, in addition to a lack of operational history, raises substantial doubt about its ability to continue as a going concern. In the absence of significant revenue and profits, and since it does not expect to generate significant revenues in the foreseeable future, the Company, in order to fund operations, will be completely dependent on additional debt and equity financing arrangements. There is no assurance that any financing will be sufficient to fund its capital expenditures, working capital and other cash requirements for the fiscal year ending December 31, 2004. No assurance can be given that any such additional funding will be available or that, if available, can be obtained on terms favorable to ImmuneRegen. If ImmuneRegen is unable to raise needed funds on acceptable terms, ImmuneRegen will not be able to develop or enhance its products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require the Registrant to take drastic steps such as reducing ImmuneRegen's level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, ImmuneRegen will not be able to continue operations.

### ITEM 7. FINANCIAL STATEMENTS

The financial statements of the Company are attached hereto as pages F-1 through F-24.

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RUSSELL BEDFORD STEFANOU MIRCHANDANI LLP  
Certified Public Accountants

#### REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS

Board of Directors and Shareholders  
IR Biosciences Holdings Inc.

Scottsdale, Arizona

We have audited the accompanying consolidated balance sheet of IR Biosciences Holdings Inc. and Subsidiary (a development stage company) (the "Company") as of December 31, 2003 and the related consolidated statements of losses, deficiency

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in stockholders' equity, and cash flows for the year ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company at December 31, 2003 and the consolidated results of its operations and its cash flows for the year ended December 31, 2003 in conformity with accounting principles generally accepted in the United States of America. We express no opinion on the cumulative period from inception through December 31, 2002.

The accompanying consolidated financial statements for the year ended December 31, 2003 have been prepared assuming that the Company will continue as a going concern. As shown in the financial statements, the Company has incurred net losses since its inception. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to this matter are described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/RUSSELL BEDFORD STEFANOU MIRCHANDANI LLP

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Russell Bedford Stefanou Mirchandani LLP  
Certified Public Accountants

New York, New York  
May 18, 2004

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### INDEPENDENT AUDITORS' REPORT

Board of Directors  
ImmuneRegen BioSciences, Inc.  
Scottsdale, Arizona

We have audited the accompanying balance sheet of ImmuneRegen BioSciences, Inc. as of December 31, 2002, and the related statements of operations, stockholders' equity (deficit), and cash flows for the period from October 30, 2002 (inception) to December 31, 2002. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements based on our audits.

We conducted our audit in accordance with auditing standards generally accepted in the 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

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test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of ImmuneRegen BioSciences, Inc. as of December 31, 2002, and the results of its operations and cash flows for the period from October 30, 2002 (inception) to December 31, 2002, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the accompanying financial statements, the Company's significant operating losses raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments to asset carrying amounts or the amount and classification of liabilities that might result from the outcome of this uncertainty.

/s/ Stonefield Josephson, Inc.

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 Stonefield Josephson, Inc.  
 Certified Public Accountants  
 Irvine, California  
 December 8, 2003

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### IR BioSciences Holdings, Inc. and Subsidiary (A Development Stage Company) Consolidated Balance Sheet

	December 31, 2003
	-----
<b>Assets</b>	
<b>Current assets</b>	
Cash and cash equivalents	\$ 10,534
Prepaid services and other assets	35,843
	-----
Total current assets	46,377
Licensed proprietary rights, net	8,247
Capitalized website costs, net	11,250
Furniture and equipment, net	2,795
	-----
<b>Total assets</b>	<b>\$ 68,669</b>
	=====
<b>Liabilities and Stockholders' Deficit</b>	
<b>Current liabilities</b>	
Accounts payable and accrued liabilities	538,441
Notes payable to shareholder	62,171
Notes payable, net of discount	311,805
	-----
Total current liabilities	912,417
Commitments and Contingencies	
Stockholders' deficit	



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Preferred stock, 0.001 par value:	
10,000,000 shares authorized,	
no shares issued and outstanding	--
Common stock, \$0.001 par value;	
100,000,000 shares authorized;	
11,715,650 shares issued and outstanding	11,715
Additional paid-in capital	1,047,157
Deficit accumulated during the development stage	(1,902,620)
	-----
Total stockholder's deficit	(843,748)
	-----
Total liabilities and stockholders' deficit	\$ 68,669
	=====

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

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IR BioSciences Holdings, Inc. and Subsidiary  
(A Development Stage Company)  
Consolidated Statements of Operations

	For the Twelve Months Ended December 31, 2003	From the Date of Inception October 30, 2002) to December 31, 2002	Cumulative from Inception October 30, 2002 December 31, 2003
	-----	-----	-----
Revenues	\$ --	\$ --	\$ --
Operating expenses:			
Selling, general and administrative expenses	1,348,078	45,718	1,393,796
Merger fees and costs	350,000	0	350,000
Financing cost	90,000	0	90,000
	-----	-----	-----
Total operating expenses	1,788,078	45,718	1,833,796
	-----	-----	-----
Operating loss	(1,788,078)	(45,718)	(1,833,796)
Interest expense	68,624	200	68,824
	-----	-----	-----
Loss before income taxes	(1,856,702)	(45,918)	(1,902,620)
Provision for income taxes	--	--	--
	-----	-----	-----
Net loss during development stage	\$ (1,856,702)	\$ (45,918)	\$ (1,902,620)
	=====	=====	=====
Net loss per share - basic and diluted	\$ (0.17)	\$ (0.02)	\$ (0.02)
	=====	=====	=====
Weighted average shares outstanding - basic and diluted	10,658,646	2,212,042	9,432,298
	=====	=====	=====

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

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IR BioSciences Holdings, Inc. and Subsidiary  
(A Development Stage Company)  
Consolidated Statements of Cash Flows

	For the Twelve Months Ended December 31, 2003 -----	From the Date of Inception October 30, 2002) to December 31, 2002 -----
Cash flows from operating activities:		
Net loss during development stage	\$(1,856,702)	(45,918)
ADJUSTMENTS TO RECONCILE NET LOSS TO TO NET CASH USED IN OPERATING ACTIVITIES:		
Non-cash compensation	105,641	782
Amortization of deferred compensation	9,000	--
Interest expense	68,624	--
Amortization of discount on notes payable	302,302	--
Depreciation and amortization	12,685	77
Changes in operating assets and liabilities:	--	
Prepaid services and other assets	(35,842)	--
Accounts payable and accrued expenses	397,402	8,786
	-----	-----
NET CASH USED IN OPERATING ACTIVITIES	(996,890)	(36,273)
Cash flows from investing activities:		
Acquisition of property and equipment	(3,304)	--
	-----	-----
NET CASH USED IN INVESTING ACTIVITIES	(3,304)	--
Cash flows from financing activities:		
Proceeds from notes payable	1,186,000	15,000
Principal payments on notes payable	(250,000)	--
Shares of stock issued for cash	65,000	31,001
Officer repayment of amounts paid on his behalf	19,880	--
Cash paid on behalf of officer	(19,880)	--
Cash paid on amount due to officer	(22,427)	22,427
	-----	-----
NET CASH PROVIDED BY FINANCING ACTIVITIES	978,573	68,428
Net increase in cash and cash equivalents	(21,621)	32,155
Cash and cash equivalents at beginning of period	32,155	--
	-----	-----
Cash and cash equivalents at end of period	\$ 10,534	\$ 32,155

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Cash paid during the period for:	=====	=====
Interest	\$    41,793	--
	=====	=====
Taxes	\$          --	--
	=====	=====

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

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IR BioSciences Holdings, Inc. and Subsidiary  
(A Development Stage Company)  
Consolidated Statements of Cash Flows (continued)

NON-CASH INVESTING AND FINANCING ACTIVITIES:

For the period ending December 31, 2002:

-----  
In December 2002, the Company issued 8,306,138 shares of common stock with a fair value of \$9,250 to the Company's founders for a license to certain proprietary rights.

In December 2002, the Company issued 702,655 shares of common stock with a fair value of \$782 to a Company founder for services provided.

In December 2002, the Company issued 26,939 shares of common stock with a fair value of \$9,000 to a service provider.

In December 2002, the Company issued 92,789 shares of common stock with a fair value of \$31,001 to four service providers.

For the period ending December 31, 2003:

-----  
During January 2003, the Company issued 49,388 shares of its common stock with a fair value of \$13,750 to 2 service providers.

During March 2003, the Company issued 77,225 shares of its common stock with a fair value of \$21,500 to a service provider.

In April 2003, the Company issued 7,184 shares of its common stock with a fair value of \$2,000 to a service provider.

In April 2003, the Company converted a note payable in the amount of \$200,000 into 718,368 shares of common stock.

In June 2003, the Company recorded a beneficial conversion feature of its convertible notes payable in the amount of \$60,560 as a discount to the notes payable.

In July 2003, the Company effected a reverse split of its common stock in the ratio of .897960746 to one. The net effect was a reduction in the number of shares of common stock outstanding of 1,196,748.

In July 2003, the Company completed the Merger with GPN Network, Inc. Pursuant to the Merger, the Company assumed the following assets and liabilities of GPN Network: Net accounts payable of \$60,492, due to related part of \$4,486, and

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note payable of \$55,821 in exchange for 1,184,065 shares of the Company's common stock and \$350,000 in cash. The Company expensed the \$350,000 cash payment, and recorded an increase of \$1,184 for the par value of the common stock and a decrease of \$121,983 to addition paid-in capital.

In October 2003, the Company recorded the value of warrants issued with notes payable as an increase to paid-in capital of \$189,937.

In October through December 2003, the Company recorded the value of warrants issued with notes payable as an increase to paid-in capital of \$207,457.

In October through December 2003, the Company recorded the value of warrants contributed by the Company's founders as an increase to paid-in capital of \$183,543.

In October through December 2003, the Company recorded the value of warrants issued with notes payable as in increase to paid-in capital of \$85,861.

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IR BioSciences Holdings, Inc. and Subsidiary  
(A Development Stage Company)  
Consolidated Statement of Stockholders' Equity (Deficit)  
From date of inception (October 30, 2002) to December 31, 2003

	Common Stock		Additional	Defer
	Shares	Amount	Paid-In	Compe
	-----	-----	-----	-----
Balance at October 30, 2002 (date of inception)	--	\$ --	--	\$
Shares of common stock issued to founders for license of proprietary rights in December 2002	8,306,138	8,306	944	
Shares of common stock issued to founders for services rendered in December 2002	702,655	703	79	
Shares of common stock issued to consultants for services rendered in December 2002	26,939	27	8,973	
Sale of common stock for cash in December 2002	92,789	92	30,909	
Net loss for the period from inception (October 30, 2002) to December 31, 2002	--	--	--	
Balance at December 31, 2002 (reflective of reverse stock split)	9,128,521	9,128	40,905	
Shares granted to consultants for services rendered in January 2003	49,388	49	13,701	
Sale of shares of common stock for cash in January 2003	164,776	165	49,835	
Shares granted to consultants for services rendered in March 2003	77,225	78	21,422	

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Conversion of notes payable to common stock in April 2003	718,368	718	199,282
Shares granted to consultants for services rendered in April 2003	7,184	7	2,023
Sale of shares of common stock for cash in May 2003	8,980	9	4,991
Sale of shares of common stock for cash in June 2003	17,959	18	9,982
Conversion of notes payable to common stock in June 2003	359,184	359	99,641
Beneficial conversion feature associated with notes issued in June 2003	--	--	60,560
Amortization of deferred compensation	--	--	--
Costs of GPN Merger in July 2003	1,184,065	1,184	(121,983)
Value of warrants issued with extended notes payable in October 2003			189,937
Value of Company warrants issued in conjunction with fourth quarter notes payable issued October through December 2003			207,457
Value of warrants contributed by founders in conjunction with fourth quarter notes payable issued October through December 2003			183,543
Value of warrants issued for services in October through December 2003			85,861
Net loss for the twelve month period ending December 31, 2003			
Balance at December 31, 2003	11,715,650	11,715	1,047,157

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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 YEAR ENDED DECEMBER 31, 2003 AND  
FOR THE PERIOD FROM OCTOBER 30, 2002  
(INCEPTION) TO DECEMBER 31, 2002 AND 2003

1. Summary of Significant Accounting Policies:

NATURE OF BUSINESS

IR Biosciences Holdings Inc. ("Company") formerly GPN Network, Inc. ("GPN") is currently a development stage company under the provisions of Statement of Financial Accounting Standards ("SFAS") No. 7. The

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Company, which was incorporated under the laws of the State of Delaware on October 30, 2002, is a biotechnology company and plans to develop and market applications utilizing modified substance P, a naturally occurring immunomodulator.

### GOING CONCERN

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern. However, the Company has no established source of revenue. This matter raises substantial doubt about the Company's ability to continue as a going concern. These financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts, or amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Management plans to take the following steps that it believes will be sufficient to provide the Company with the ability to continue in existence: Management intends to continue to raise additional financing through private debt or equity financing or other means and interests that it deems necessary, with a view to moving forward and sustaining a prolonged growth in its strategy phases. The Company believes that its status as a publicly traded company will improve its chances of raising funds through either equity or debt financings.

### ACQUISITION AND CORPORATE RESTRUCTURE

On July 20, 2003 ImmuneRegen Biosciences Inc. ("ImmuneRegen") entered into an Agreement of Plan and Merger ("Agreement") with GPN Network, Inc. ("GPN") an inactive publicly registered shell corporation with no significant assets or operations. In accordance with SFAS No. 141, the Company was the acquiring entity. While the transaction is accounted for using the purchase method of accounting, in substance the Agreement is a recapitalization of the Company's capital structure.

For accounting purposes, the Company has accounted for the transaction as a reverse acquisition and the Company shall be the surviving entity. The total purchase price and carrying value of net assets acquired was \$ 0. From July 2001 until the date of the Agreement the Company was inactive. The Company did not recognize goodwill or any intangible assets in connection with the