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IR BIOSCIENCES HOLDINGS INC  
Form 10KSB/A  
July 20, 2005

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

FORM 10-KSB/A  
Amendment No. 1

(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

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

Securities registered under Section 12(b) of the Exchange Act:

NONE

Securities registered pursuant to Section 12(g) of the Exchange Act:

COMMON STOCK, \$ 0.001 PAR VALUE PER SHARE

-----  
(Title of class)

Check whether the issuer: (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

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or any amendment to this Form 10-KSB. [ X ]

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

The aggregate market value of the Registrant's issued and outstanding shares of common stock held by non-affiliates of the Registrant as of May 6, 2004 (based on the average of the bid and asked prices as reported by the NASD OTC Bulletin Board as of that date) was approximately \$2,309,569.

The number of shares outstanding of Registrant's Common Stock, par value \$0.001 as of May 3, 2004: 27,581,274.

Documents Incorporated by reference: None

Transitional Small Business Disclosure Format Yes \_\_\_\_\_ No  \_\_\_\_\_

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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

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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,

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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

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company that offers services ranging from pre-clinical and toxicology studies to 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

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people with ARS decreases with increasing radiation dose. Most people who do not 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)

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because of respiratory failure. ARDS is not a specific disease; instead, it is a 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 Homospira 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

#### 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

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drug industry, the merger of companies into larger and more competitive ones, 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

#### 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.

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

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States and Europe. ImmuneRegen is currently investigating regulatory and other 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

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approved for commercial sale.

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

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

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and to provide an adequate basis for physician labeling. Each trial is conducted 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 Homspira 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

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typically used by manufacturers seeking approval of a generic drug. The statute 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. Our sole full time employee is our Chief Executive Officer, Michael K. Wilhelm. None of its employees are covered by a collective bargaining agreement.

### RISK FACTORS

In evaluating our business, you should consider the following discussions of risks, in addition to other information contained in this report as well as our other public filings with the Securities and Exchange Commission. Any of the following risks could materially adversely affect our business, financial condition, results of operations and prospects.

WE HAVE AN ACCUMULATED DEFICIT, ARE NOT CURRENTLY PROFITABLE AND EXPECT TO INCUR SIGNIFICANT EXPENSES IN THE NEAR FUTURE.

We have incurred a substantial net loss for the period from our inception in October 2002 to December 31, 2003, and currently experiencing negative cash flow. We expect to continue to experience negative cash flow and operating losses through at least 2004 and possibly thereafter. As a result, we will need to generate significant revenues to achieve profitability. If our revenues grow more slowly than we anticipate, or if our operating expenses exceed our expectations, we may experience reduced profitability.

WE MAY FAIL TO BECOME AND REMAIN PROFITABLE OR WE MAY BE UNABLE TO FUND OUR CONTINUING LOSSES, IN WHICH CASE OUR BUSINESS MAY FAIL.

We are focused on product development and have not generated any revenue to date. We have incurred operating losses since our inception. Our net loss for

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the twelve months ended December 31, 2003 was \$1,856,702. As of December 31, 2003, we had an accumulated deficit of \$1,902,620.

We currently have no product candidates for sale in the United States, and we cannot guarantee that we will ever have marketable products in the United States. We must demonstrate that our product candidates satisfy rigorous standards of safety and efficacy before the FDA and other regulatory authorities in the United States and abroad will approve the products for commercial marketing. We will need to conduct significant additional research, preclinical testing and clinical testing before we can file applications with the FDA for approval of our product candidates. In addition, to compete effectively, our future products must be easy to use, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives.

We expect to incur losses as we research, develop and seek regulatory approvals for our products. If our products fail in clinical trials or do not gain regulatory approval, or if our products do not achieve market acceptance, we will not be profitable. If we fail to become and remain profitable, or if we are unable to fund our continuing losses, our business may fail.

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

Our independent certified public accountants have stated in their report included in this Form 10-KSB that 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, 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 our ability to raise capital, our relationship with potential suppliers and customers, and have other unforeseen effects.

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OUR OPERATING EXPENSES ARE UNPREDICTABLE, WHICH MAY ADVERSELY AFFECT OUR BUSINESS, OPERATIONS AND FINANCIAL CONDITION.

As a result of our limited operating history and because of the emerging nature of the markets in which we will compete, our financial data is of limited value in planning future operating expenses. To the extent our operating expenses precede or are not rapidly followed by increased revenue, our business, results of operations and financial condition may be materially adversely affected. Our expense levels will be based in part on our expectations concerning future revenues. A significant portion of our revenue is anticipated to be derived from Homspera; however the size and extent of such revenues are wholly dependent upon the choices and demand of individuals, which are difficult to forecast accurately. We may be unable to adjust our operations in a timely manner to compensate for any unexpected shortfall in revenues. Further, business development and marketing expenses may increase significantly as we expand our operations.

WE MAY EXPERIENCE FLUCTUATION OF QUARTERLY OPERATING RESULTS WHICH MAY CAUSE OUR STOCK PRICE TO FLUCTUATE.

Our quarterly operating results may fluctuate significantly in the future as a result of a variety of factors, many of which are outside our control. These factors include: the level of demand for Homspera and any other products; our ability to attract and retain personnel with the necessary strategic, technical



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and creative skills required for effective operations; the amount and timing of expenditures by customers; the amount and timing of capital expenditures and other costs relating to the expansion of our operations; government regulation and legal developments regarding the use of Homspera; and general economic conditions. As a strategic response to changes in the competitive environment, we may from time to time make certain pricing, service, technology or marketing decisions that could have a material adverse effect on our quarterly results. Due to all of these factors, our operating results may fall below the expectations of securities analysts, stockholders and investors in any future quarter.

IF OUR PLAN IS NOT SUCCESSFUL OR MANAGEMENT IS NOT EFFECTIVE, THE VALUE OF OUR COMMON STOCK MAY DECLINE.

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

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

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

WE WILL BE REQUIRED TO RAISE ADDITIONAL CAPITAL TO FUND OUR OPERATIONS. IF WE CANNOT RAISE NEEDED ADDITIONAL CAPITAL IN THE FUTURE, WE WILL BE REQUIRED TO CEASE OPERATIONS.

We require substantial working capital to fund our operations. Since we do not expect to generate significant revenues in the foreseeable future, in order to fund operations, we will be completely dependent on additional debt and equity financing arrangements. As of December 31, 2003, our cash and cash equivalents totaled approximately \$10,534. Based on our current plans, we believe these financial resources, and interest earned thereon, will be sufficient to meet our

operating expenses and capital requirements for at least the next 30 days. There is no assurance that any financing will be sufficient to fund our 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 us. If we are unable to raise needed funds on acceptable terms, we will not be able to develop or enhance our products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as

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reducing our level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, we will not be able to continue operations.

We expect to require substantial additional funds in order to finance our drug discovery and development programs, fund operating expenses, pursue regulatory clearances, develop manufacturing, marketing and sales capabilities, and prosecute and defend our intellectual property rights. We may seek additional funding through public or private financing or through collaborative arrangements with strategic partners.

You should be aware that in the future:

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

If we cannot raise additional funds when needed, or on acceptable terms, we will not be able to continue to develop our drug candidates. We require substantial working capital to fund our operations. Since we do not expect to generate significant revenues in the foreseeable future, in order to fund operations, we will be completely dependent on additional debt and equity financing arrangements. There is no assurance that any financing will be sufficient to fund our capital expenditures, working capital and other cash requirements for the next 12 months. Our working capital as of December 31, 2003 was \$(866,040). No assurance can be given that any such additional funding will be available or that, if available, can be obtained on terms favorable to us. If we are unable to raise needed funds on acceptable terms, we will not be able to develop or enhance our products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, we will not be able to continue operations.

ALL OUR APPLICATIONS ARE ALL DERIVED FROM THE USE OF HOMSPERA. IF HOMSPERA IS FOUND TO BE UNSAFE OR INEFFECTIVE, OUR BUSINESS WOULD BE MATERIALLY HARMED.

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

IF WE FAIL TO SUCCESSFULLY DEVELOP AND COMMERCIALIZE PRODUCTS, WE WILL HAVE TO CEASE OPERATIONS.

Our failure to develop and commercialize products successfully will cause us to cease operations. Our potential therapies utilizing Homspira will require significant additional research and development efforts and regulatory approvals prior to potential commercialization in the future. We cannot guarantee that we, or our corporate collaborators, if any, will ever obtain any regulatory approvals of Homspira. We currently are focusing our core competencies on Homspira although there may be no assurance that we will be successful in so doing.

Our therapies and technologies utilizing Homspira is at early stages of development and may not be shown to be safe or effective and may never receive regulatory approval. Our technologies utilizing Homspira have 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

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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 our 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 we are to develop any products. Delays in planned patient enrollment in our clinical trials may result in increased costs, program delays or both. None of our potential products 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, our potential products may not achieve market acceptance. Any products resulting from our programs may not be successfully developed or commercially available for a number of years, if at all.

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

THE MARKET FOR TREATING ACUTE RADIATION SYNDROME IS UNCERTAIN AND WE MAY NOT BE ABLE TO SUCCESSFULLY COMMERCIALIZE RADILEX.

We do not believe any drug has ever been approved and commercialized for the treatment of severe acute radiation injury. In addition, the incidence of large-scale exposure to nuclear or radiological events has been low. Accordingly, even if Radilex, our lead drug candidate to treat Acute Radiation Syndrome (ARS), is approved by the FDA, we cannot predict with any certainty the size of this market. The potential market for Radilex is largely dependent on the size of stockpiling orders, if any, procured by the U.S. and foreign governments. While a number of governments have historically stockpiled drugs to treat indications such as smallpox, anthrax exposure, plague, tularemia and certain long-term effects of radiation exposure, we are unaware of any significant stockpiling orders for drugs to treat ARS. While we have filed a formal response to the U.S. Department of Health and Human Services Request for Information (RFI) for therapeutics to treat ARS, at least one other company has responded to this RFI, and we cannot guarantee that our response to this RFI will result in a U.S. Department of Health and Human Services Request for Proposal (RFP) or any stockpiling orders. A decision by the U.S. Government to enter into a commitment to purchase Radilex prior to FDA approval is largely out of our control. Our development plans and timelines may vary substantially depending on whether we receive such a commitment and the size of such commitment, if any. In addition, even if Radilex is approved by regulatory authorities, we cannot guarantee that we will receive any stockpiling orders for Radilex, that any such order would be profitable to us or that Radilex will achieve market acceptance by the general public.

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

Clinical testing, manufacture, promotion, export and sale of our proposed products are subject to extensive regulation by numerous governmental authorities in the United States, principally the FDA, and corresponding state and foreign regulatory agencies. This regulation may delay or prevent us from commercializing proposed products. Noncompliance with applicable requirements

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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. We may not receive necessary FDA clearances for any of our 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 our 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. We may encounter significant delays or excessive costs in our efforts to secure necessary approvals. Regulatory requirements are evolving and uncertain. Future United States or foreign legislative or administrative acts could also prevent or delay regulatory approval of our products. We may not be able to obtain the necessary approvals for clinical trials, manufacturing or marketing of any of our 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.

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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.

IF WE OBTAIN REGULATORY APPROVAL OF OUR PRODUCTS, THEY WILL BE SUBJECT TO CONTINUING REVIEW AND EXTENSIVE REGULATORY REQUIREMENTS, WHICH COULD AFFECT THE MANUFACTURING AND MARKETING OF OUR PRODUCTS.

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. The FDA could withdraw a previously approved product from the market upon receipt of newly discovered information, including a failure to comply with regulatory requirements, the occurrence of unanticipated problems with products following approval, or other reasons, which could adversely affect our operating results.

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 us. We, or our contract manufacturers, if any, may not be able to maintain compliance with the FDA's GMP requirements on a continuing basis. Failure to maintain compliance could have a material adverse effect on us.

Additionally, the FDA's policies may change and additional government

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

IF WE FAIL TO OBTAIN APPROVAL FROM FOREIGN REGULATORY AUTHORITIES, WE WILL NOT BE ALLOWED TO MARKET OR SELL OUR PRODUCTS IN OTHER COUNTRIES.

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

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

SIGNIFICANT DELAY OR FAILURE TO OBTAIN REGULATORY APPROVALS WOULD IMPEDE OUR ABILITY TO GENERATE REVENUE.

The process of obtaining FDA and other regulatory approvals is time consuming, expensive and difficult to design and implement. Clinical trials are required and the marketing and manufacturing of our applications are subject to rigorous testing procedures. Significant delays in clinical trials will impede our ability to commercialize our applications and generate revenue and could significantly increase our development costs. The commencement and completion of clinical trials for our Homspera-based applications or any of our applications could be delayed or prevented by a variety of factors, including:

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- o delays in obtaining regulatory approvals to commence a study;
- o delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- o delays in the enrollment of patients;
- o lack of efficacy during clinical trials; or,
- o unforeseen safety issues.

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

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

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- o withdrawing marketing clearance.

CLINICAL TRIALS MAY FAIL TO DEMONSTRATE THE SAFETY AND EFFICACY OF OUR APPLICATIONS, WHICH COULD PREVENT OR SIGNIFICANTLY DELAY REGULATORY APPROVAL.

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

All of our applications are prone to the risks of failure inherent in biologic development. The results of early-stage clinical trials of our applications do not necessarily predict the results of later-stage clinical trials. Applications in later-stage clinical trials may fail to show desired safety and efficacy traits despite having progressed through initial clinical testing. Even if we believe the data collected from clinical trials of our applications is promising, this data may not be sufficient to support approval by the FDA or any other U.S. or foreign regulatory approval. Preclinical and clinical data can be interpreted in different ways. Accordingly, FDA officials could interpret such data in different ways than we do, which could delay, limit or prevent regulatory approval. The FDA, other regulatory authorities, or we may suspend or terminate clinical trials at any time. Any failure or significant delay in completing clinical trials for our applications, or in receiving regulatory approval for the sale of any products resulting from our applications, may severely harm our business and reputation.

DELAYS IN THE CONDUCT OR COMPLETION OF OUR PRECLINICAL OR CLINICAL STUDIES OR THE ANALYSIS OF THE DATA FROM OUR PRECLINICAL OR CLINICAL STUDIES MAY RESULT IN DELAYS IN OUR PLANNED FILINGS FOR REGULATORY APPROVALS, OR ADVERSELY AFFECT OUR ABILITY TO ENTER INTO COLLABORATIVE ARRANGEMENTS.

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

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

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

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

IF THE MANUFACTURERS OF OUR PRODUCTS DO NOT COMPLY WITH CURRENT GOOD MANUFACTURING PRACTICES REGULATIONS, OR CANNOT PRODUCE THE AMOUNT OF PRODUCTS WE NEED TO CONTINUE OUR DEVELOPMENT, WE WILL FALL BEHIND ON OUR BUSINESS OBJECTIVES.

Manufacturers producing our drug candidates must follow current Good Manufacturing Practices, or GMP, regulations enforced by the FDA and foreign equivalents. If a manufacturer of our drug candidates does not conform to the GMP regulations and cannot be brought up to such a standard, we will be required to find alternative manufacturers that do conform. This may be a long and difficult process, and may delay our ability to receive FDA or foreign regulatory approval of our products.

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

OUR LACK OF COMMERCIAL MANUFACTURING, SALES, DISTRIBUTION AND MARKETING EXPERIENCE MAY PREVENT US FROM SUCCESSFULLY COMMERCIALIZING PRODUCTS.

The manufacturing process of our proposed products is expected to involve a number of steps and requires compliance with stringent quality control specifications imposed by us and by the FDA. We have no experience in the sales, marketing and distribution of pharmaceutical or biotechnology products. We have not manufactured any of our products in commercial quantities. We 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.

WE RELY ON THIRD PARTY MANUFACTURERS FOR THE MANUFACTURE OF HOMSPERA. OUR INABILITY TO MANUFACTURE HOMSPERA, AND OUR DEPENDENCE ON SUCH MANUFACTURERS, MAY DELAY OR IMPAIR OUR ABILITY TO GENERATE REVENUES, OR ADVERSELY AFFECT OUR PROFITABILITY.

We may enter into arrangements with contract manufacturing companies in order to meet requirements for our products or to attempt to improve manufacturing efficiency. If we choose to contract for manufacturing services, we may encounter costs, delays and/or other difficulties in producing, packaging and distributing our clinical trials and finished product. 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 our product supplies. Our potential dependence upon third parties for the manufacture of our proposed products may adversely affect our profit margins and our ability to develop and deliver proposed products on a timely and competitive basis. For the manufacture of the applications under development, we obtain synthetic peptides from third party manufacturers. A synthesized version of Homspira 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. If any of these proposed manufacturing operations prove inadequate, there may be no assurance that any other arrangements may be established on a timely basis or that we could establish other manufacturing capacity on a timely basis. Although, we believe 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, our dependence

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on such manufacturers, may delay or impair our ability to generate revenues, or adversely affect our profitability.

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

Our ability to earn sufficient revenue on Homspira 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 us from successfully commercializing Homspira or any proposed products. Third-party payers are increasingly challenging the prices of medical products and services. If purchasers or users of Homspira 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.

THE MEDICAL COMMUNITY MAY NOT ACCEPT AND UTILIZE HOMSPERA, WHICH WOULD PREVENT US FROM SUCCESSFULLY COMMERCIALIZING THE PRODUCT.

Our ability to market and commercialize Homspira depends on the acceptance and utilization of Homspira by the medical community. We will need to develop commercialization initiatives designed to increase awareness about us and Homspira among targeted audiences, including public health activists and community-based outreach groups in addition to the investment community.

Currently, we have not developed any such initiatives. Without such acceptance of Homspira, the product upon which we expect to be substantially dependent, we may not be able to successfully commercialize Homspira or generate revenue.

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PRODUCT LIABILITY EXPOSURE MAY EXPOSE US TO SIGNIFICANT LIABILITY OR COSTS.

We face an inherent business risk of exposure to product liability and other claims and lawsuits in the event that the development or use of our technology or prospective products is alleged to have resulted in adverse effects. We may not be able to avoid significant liability exposure. We may not have sufficient insurance coverage and we may not be able to obtain sufficient coverage at a reasonable cost. An inability to obtain product liability insurance at acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of our products. A product liability claim could hurt our financial performance. Even if we avoids liability exposure, significant costs could be incurred that could hurt our financial performance.

AS A RESULT OF OUR INTENSELY COMPETITIVE INDUSTRY, WE MAY NOT GAIN ENOUGH MARKETSHARE TO BE PROFITABLE.

The biotechnology and pharmaceutical industries are intensely competitive. We have numerous competitors in the United States and elsewhere. Because we are pursuing potentially large markets, our competitors include major multinational pharmaceutical companies, specialized biotechnology firms and universities and other research institutions. Several of these entities have already successfully marketed and commercialized products that will compete with our products, assuming that our products gain regulatory approval. Competitors such as Hollis-Eden Pharmaceuticals, Inc. have developed or are developing products for the treatment of severe acute radiation injury. Companies such as VaxGen, Inc., Acambis plc and Emergent BioSolutions have developed or are developing vaccines



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against infectious diseases, including anthrax.

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

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

IF WE FAIL TO ATTRACT AND RETAIN HIGHLY SKILLED SCIENTIFIC PERSONNEL, OUR GROWTH COULD BE LIMITED, WHICH MAY ADVERSELY AFFECT OUR RESULTS OF OPERATIONS AND FINANCIAL POSITION.

Our future success depends in large part upon our ability to attract and retain highly skilled scientific personnel. The competition in the scientific industry for such personnel is intense, and we cannot be sure that we will be successful in attracting and retaining such personnel. Most of our consultants and employees and several of our executive officers began working for us recently, and all employees are subject to "at will" employment. We cannot guarantee that we will be able to replace any of our scientific personnel in the event their services become unavailable.

WE MAY FAIL TO PROTECT ADEQUATELY OUR PROPRIETARY TECHNOLOGY, WHICH WOULD ALLOW COMPETITORS TO TAKE ADVANTAGE OF RESEARCH AND DEVELOPMENT EFFORTS.

We own or have obtained a license to 4 issued U.S. and foreign patents and 8 pending U.S. and foreign patent applications. Our success will depend in part on our ability to obtain additional United States and foreign patent protection for our drug candidates and processes, preserve our trade secrets and operate without infringing the proprietary rights of third parties. We place considerable importance on obtaining patent protection for significant new technologies, products and processes.

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

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biotechnology inventions and the scope of claims made under such patents are still developing. In some of the countries in which we intend to market our products, pharmaceuticals are either not patentable or have only recently become patentable. Past enforcement of intellectual property rights in many of these countries has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries may be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions.

The U.S. Patent and Trademark Office, commonly referred to as the USPTO, and the courts have not consistently treated the breadth of claims allowed in biotechnology patents. If the USPTO or the courts begin to allow broader claims, the incidence and cost of patent interference proceedings and the risk of infringement litigation will likely increase. On the other hand, if the USPTO or the courts begin to allow narrower claims, the value of our proprietary rights may be limited. Any changes in, or unexpected interpretations of the patent laws may adversely affect our ability to enforce our patent position.

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

OUR PATENTS AND PROPRIETARY TECHNOLOGY MAY NOT BE ENFORCEABLE AND THE PATENTS AND PROPRIETARY TECHNOLOGY OF OTHERS MAY PREVENT US FROM COMMERCIALIZING PRODUCTS.

Although we believe our inventions to be protected and our patents enforceable, the failure to obtain meaningful patent protection products and processes would greatly diminish the value of our potential products and processes.

In addition, whether or not our applications are issued, or issued with limited coverage, others may receive patents, which contain claims applicable to our products. Patents we are not aware of may adversely affect our 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. We also rely upon non-patented trade secrets and know how, and others may independently develop substantially equivalent trade secrets or know how. We also rely on protecting our proprietary technology in part through confidentiality agreements with our current and former corporate collaborators, employees, consultants and certain contractors. These agreements may be breached, and we may not have adequate remedies for any such breaches. Litigation may be necessary to defend against claims of infringement, to enforce our patents or to protect trade secrets. Litigation or other disputes regarding patents and other proprietary rights may be expensive, cause delays in bringing products to market and harm our ability to operate. In addition, litigation could result in substantial costs and diversion of management efforts regardless of the results of the litigation. An adverse result in litigation could subject us to significant liabilities to third parties, require disputed rights to be licensed or require us to cease using certain technologies.

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

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

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

COMPLIANCE WITH ENVIRONMENTAL LAWS OR REGULATIONS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS.

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

WE DEPEND ON THE CONTINUED SERVICES OF OUR EXECUTIVE OFFICERS AND THE LOSS OF A KEY EXECUTIVE COULD SEVERELY IMPACT OUR OPERATIONS.

The execution of our present business plan depends on the continued services of Michael K. Wilhelm, our Chief Executive Officer and President, Mark L. Witten, Ph.D., our acting Chief Scientific Officer. We do not currently maintain key-man insurance on their lives. While we have entered into employment agreements with each of them, the loss of any of their services would be detrimental to us and could have a material adverse effect on our business, financial condition and results of operations.

OUR COMPLIANCE WITH SECURITIES LAWS, RULES AND REGULATIONS TO WHICH WE ARE SUBJECT COULD SUBSTANTIALLY INCREASE OUR OPERATING EXPENSES AND DIVERT

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MANAGEMENT'S ATTENTION FROM THE OPERATION OF OUR BUSINESS.

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

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

Our officers, directors and principal stockholders, and their affiliates, in the aggregate, own over a majority of the outstanding shares of 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 our 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 our business, even if such a transaction would be beneficial to other stockholders.

TRADING IN OUR SECURITIES COULD BE SUBJECT TO EXTREME PRICE FLUCTUATIONS THAT COULD ADVERSELY AFFECT YOUR INVESTMENT.

The market prices for securities of life sciences companies, particularly those that are not profitable, have been highly volatile, especially recently. Publicized events and announcements may have a significant impact on the market price of our common stock. For example:

- o biological or medical discoveries by competitors;
- o public concern about the safety of our drug candidates;
- o delays in the conduct or analysis of our preclinical or clinical studies;
- o unfavorable results from preclinical or clinical studies;
- o unfavorable developments concerning patents or other proprietary rights;
- or o unfavorable domestic or foreign regulatory developments;

may have the effect of temporarily or permanently driving down the price of our common stock. In addition, the stock market from time to time experiences extreme price and volume fluctuations which particularly affect the market prices for emerging and life sciences companies, such as ours, and which are often unrelated to the operating performance of the affected companies. For example, our stock price has ranged from \$0.01 to \$4.50 between January 1, 2003 and December 31, 2003.

These broad market fluctuations may adversely affect the ability of a stockholder to dispose of his shares at a price equal to or above the price at which the shares were purchased. In addition, in the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Any litigation against our company, including this type of litigation, could result

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in substantial costs and a diversion of management's attention and resources, which could materially adversely affect our business, financial condition and results of operations.

A LIMITED PRIOR PUBLIC MARKET AND TRADING MARKET MAY CAUSE VOLATILITY IN THE PRICE OF OUR COMMON STOCK.

Our common stock is currently traded on a limited basis on the OTC Bulletin Board (the "OTCBB") under the symbol "IRBO". The OTCBB is an inter-dealer, Over-The-Counter market that provides significantly less liquidity than the NASDAQ Stock Market. Quotes for stocks included on the OTCBB 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 OTCBB may be difficult to obtain and holders of common stock may be unable to resell their securities at or near their original offering price or at any price. The NASD has enacted recent changes that 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 quotation of our common stock on the OTCBB does not assure that a meaningful, consistent and liquid trading market currently exists, and in recent years such market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is thus subject to this volatility.

BROKER-DEALER REQUIREMENTS FOR "PENNY STOCK" TRANSACTIONS MAY AFFECT THE ABILITY OF OUR INVESTORS TO RESELL THEIR SECURITIES.

Our 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. 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. Compliance with this and other requirements may make it more difficult for holders of our common stock to resell their shares to third parties or to otherwise dispose of them in the market or otherwise.

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

We expect to continue to incur product development and selling, general and administrative costs, and in order to satisfy our funding requirements, we will need to sell additional equity securities, which may be subject to similar registration rights. The sale or the proposed sale of substantial amounts of our common stock in the public markets may adversely affect the market price of our common stock.

From time to time, certain stockholders of our company may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Act ("Rule 144"), subject to certain limitations. In general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who has satisfied a one-year holding periods may, under certain circumstances, sell within any three-month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of our common stock or the average weekly

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trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitations, by a non-affiliate of our company who has satisfied a two-year holding period. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have an adverse effect on the market price of our securities.

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

### 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.

## 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

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1st Quarter	\$0.20	\$0.20
2nd Quarter	4.00	0.20
3rd Quarter	9.00	1.10
4th Quarter	2.25	0.55

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2002

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

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#### 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.

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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.

In December 2002, we entered into a royalty-free license agreement with David Harris and Mark Witten, who are our two founders and largest shareholders. Under the terms of the license agreement, Messrs. Harris and Witten granted to us an exclusive license to use and sublicense certain patents, medical applications, and other technologies developed by them. Our obligations under this agreement include (i) reasonable efforts to protect any licensed patents or other associated property rights; (ii) reasonable efforts to maintain confidentiality of any proprietary information; (iii) upon the granting by the U. S. Food and Drug Administration to us the right to market a product, we will maintain a broad form general liability and product liability insurance.

On December 16, 2002 we entered into consulting agreements with David Harris and Mark Witten, who were our two founders and research scientists. The consulting agreements are on a month-to-month basis. Under the terms of these agreements,



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Messrs. Harris and Witten agreed to place at the disposal of us their judgment and expertise in the area of acute lung injury. In consideration for these services, we agreed to pay each of them a non-refundable fee of \$5,000 per month.

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Pursuant to consulting agreements entered into with David Harris and Mark Witten, who are our two founders and chief research scientists, during the period from October 30, 2002 (inception) to December 31, 2002, we accrued \$5,000 in consulting fees. During the period from January 1, 2003 to December 31, 2003, we accrued an additional \$120,000 in consulting fees. We had accrued payables collectively due to Drs. Harris and Witten of \$125,000 and \$5,000 as of December 31, 2003 and 2002, respectively.

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

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.

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### Revenue

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

### Selling, General, and Administrative Expenses

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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 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

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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

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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

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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

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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.

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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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 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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STONEFIELD JOSEPHSON, INC.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors  
ImmuneRegen BioSciences, Inc.

# Edgar Filing: IR BIOSCIENCES HOLDINGS INC - Form 10KSB/A

Scottsdale, Arizona

We have audited the balance sheet of ImmuneRegen BioSciences, Inc. as of December 31, 2002 (not included herein), and the accompanying 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 these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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 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.

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.

-----  
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
	-----
Assets	
Current assets	
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

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Furniture and equipment, net	2,795
	-----
Total assets	\$ 68,669
	=====
Liabilities and Stockholders' Deficit	
Current liabilities	
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	
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
	-----	-----	-----

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Loss before income taxes	(1,856,702)	(45,918)	(1,902,6
Provision for income taxes	----- --	----- --	-----
Net loss during development stage	=====	=====	=====
Net loss per share - basic and diluted	\$ (0.17)	\$ (0.02)	\$ (0.
Weighted average shares outstanding - basic and diluted	=====	=====	=====
	10,658,646	2,212,042	9,432,2

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	Cu fr Oc De
	-----	-----	
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	

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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
	=====	=====
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:

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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:

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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



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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 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 an 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 Paid-In Capital	Defer Compe
	Shares	Amount		
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				

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(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
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.

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(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 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 transaction.

Effective with the Agreement, all previously outstanding common stock, preferred stock, options and warrants owned by the Company's shareholders were exchanged for an aggregate of 10,531,585 shares of GPN common stock. The value of the stock that was issued was the historical cost of GPN's net tangible assets, which did not differ

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materially from their fair value.

Effective with the Agreement, GPN changed its name to IR Biosciences Holdings Inc.

The accompanying financial statements present the historical financial condition, results of operations and cash flows of the Company prior to the merger with GPN.

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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, continued:

USE OF ESTIMATES

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

CASH EQUIVALENTS

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

CASH CONCENTRATION

The Company maintains its cash in bank deposit accounts that, at times, may exceed federally insured limits. The Company has not experienced any losses in such accounts.

BASIC AND DILUTED LOSS PER SHARE

In accordance with SFAS No. 128, "Earnings Per Share," the basic loss per common share is computed by dividing net loss available to common stockholders by the weighted average number of common shares outstanding. Diluted loss per common share is computed similar to basic loss per common share except that the denominator is increased to include the number of additional common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive. As of December 31, 2002, the Company had no outstanding stock options or warrants. As of December 31, 2003, the Company granted warrants to employees and consultants that can be converted into additional shares of common stock. These warrants would have an anti-dilutive effect and therefore are not included in diluted loss per share.

COMPREHENSIVE INCOME

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SFAS No. 130, "Reporting Comprehensive Income," establishes standards for the reporting and display of comprehensive income and its components in the financial statements. As of December 31, 2003 and 2002 the Company has no items that represent other comprehensive income and, therefore, has not included a Statement of Comprehensive Income.

### INCOME TAXES

The Company accounts for income taxes under SFAS 109, "Accounting for Income Taxes." Under the asset and liability method of SFAS 109, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statements carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Under SFAS 109, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period the enactment occurs. A valuation allowance, if any, is provided for certain deferred tax assets if it is more likely than not that the Company will not realize tax assets through future operations.

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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, continued:

#### FAIR VALUE OF FINANCIAL INSTRUMENTS

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

#### STOCK-BASED COMPENSATION

The Company accounts for stock-based employee compensation arrangements in accordance with the provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and complies with the disclosure provisions of SFAS 123, "Accounting for Stock-Based Compensation." Under APB 25, compensation cost is recognized over the vesting period based on the excess, if any, on the date of grant of the deemed fair value of the Company's shares over the employee's exercise price. When the exercise price of the employee share options is less than the fair value price of the underlying shares on the grant date, deferred stock compensation is recognized and amortized to expense in accordance with FASB Interpretation No. 28 over the vesting period of the individual options. Accordingly, because the exercise price of the Company's employee options equals or exceeds the market price of the underlying shares on the date of grant, no compensation expense is recognized. Options or shares awards issued to non-employees are valued using the fair value method and expensed over

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the period services are provided.

### PREPAID SERVICES

Prepaid services consist of outside services that the Company has paid for in advance. At December 31, 2003 this amount was \$35,843, consisting of a legal retainer in the amount of \$18,543 and a prepaid research contract with the University of Arizona of \$17,300. These items are charged to expense as the services are performed.

### LICENSED PROPRIETARY RIGHTS

The Company has licensed from its founders certain proprietary rights which the Company intends to utilize in the execution of its business plan. Consideration for this license was the issuance of 8,306,138 shares (pre-split) of the Company's common stock. These proprietary rights are being amortized over the term of the license agreement, or ten years. The shares issued were valued at \$.001 per share (par value).

### CAPITALIZED WEBSITE COSTS

The Company capitalized certain website development costs pursuant to EITF 00-2 "Accounting for Web Site Development Costs"; these costs are amortized over two years.

### FURNITURE AND EQUIPMENT

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

Computer equipment	3 years
Furniture	7 years

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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, continued:

### ADVERTISING

The Company follows the policy of charging the costs of advertising to expenses incurred. The Company has not incurred any advertising costs during the year ended December 31, 2003 and for the period from October 30, 2002 (inception) through December 31, 2002 and 2003.

### NEW ACCOUNTING PRONOUNCEMENTS

In April 2003, the FASB issued SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities." This Statement amends and clarifies financial accounting and reporting for derivative

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instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities under SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities." This Statement amends Statement 133 for decisions made (1) as part of the Derivatives Implementation Group process that effectively required amendments to Statement 133, (2) in connection with other Board projects dealing with financial instruments, and (3) in connection with implementation issues raised in relation to the application of the definition of a derivative, in particular, the meaning of an initial net investment that is smaller than would be required for other types of contracts that would be expected to have a similar response to changes in market factors, the meaning of underlying, and the characteristics of a derivative that contains financing components. The Company does not anticipate that the adoption of this pronouncement will have a material effect on the financial statements.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." This Statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. Some of the provisions of this Statement are consistent with the current definition of liabilities in FASB Concepts Statement No. 6, Elements of Financial Statements. The remaining provisions of this Statement are consistent with the Board's proposal to revise that definition to encompass certain obligations that a reporting entity can or must settle by issuing its own equity shares, depending on the nature of the relationship established between the holder and the issuer. While the Board still plans to revise that definition through an amendment to Concepts Statement 6, the Board decided to defer issuing that amendment until it has concluded its deliberations on the next phase of this project. That next phase will deal with certain compound financial instruments including puttable shares, convertible bonds, and dual-indexed financial instruments. The Company does not anticipate that the adoption of this pronouncement will have a material effect on the financial statements.

### LONG-LIVED ASSETS

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

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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 (Continued)

NEW ACCOUNTING PRONOUNCEMENTS (Continued)

In January 2003, the FASB issued Interpretation No. 46, "Consolidation of Variable Interest Entities." Interpretation 46 changes the criteria by which one company includes another entity in its financial statements. Previously, the criteria were based on control through voting interest. Interpretation 46 requires a variable interest entity to be by a company if that company is subject to a majority of the risk of loss from the variable interest entity's activities or entitled to receive a majority of the entity's residual returns or both. A company that consolidates a variable interest entity is called the primary beneficiary of that entity. The consolidation requirements of Interpretation 46 apply immediately to variable interest entities created after January 31, 2003. The consolidation requirements apply to older entities in the first fiscal year or interim period beginning after June 15, 2003. Certain of the disclosure requirements apply in all financial statements issued after January 31, 2003, regardless of when the variable interest entity was established. The Company does not expect the adoption to have a material impact to the Company's financial position or Results of operations.

During October 2003, the FASB issued Staff Position No. FIN 46 deferring the effective date for applying the provisions of FIN 46 until the end of the first interim or annual period ending after December 31, 2003, if the variable interest was created prior to February 1, 2003, and the public entity has not issued financial statements reporting that variable interest entity in accordance with FIN 46. The FASB also indicated it would be issuing a modification to FIN 46 prior to the end of 2003. Accordingly, the Company has deferred the adoption of FIN 46 with respect to VIE's created prior to February 1, 2003. Management is currently assessing the impact, if any, FIN 46 may have on the Company; however, management does not believe there will be any material impact on its financial statements, results of operations or liquidity resulting from the adoption of this interpretation.

2. Related-Party Transactions:

EMPLOYMENT CONTRACTS

On December 16, 2002, the Company entered into an employment contract with its President and CEO (the "CEO Contract") for a period of three years terminating on December 15, 2005. The agreement calls for a salary at the rate of \$125,000 per annum for the first year, \$175,000 for the second year, and \$250,000 for the third year. The CEO Contract also provides for the following various bonus incentives:

- i) A quarterly discretionary bonus based upon the Company's performance in the previous quarter. This discretionary bonus will be in the form of stock options.



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- ii) A quarterly five-year warrant to purchase up to 4,490 shares (post reverse-split) of the Company's common stock at 75% of the fair market value of the stock on the date the warrant is granted.
- iii) At such time as the CEO introduces a financial partner to the Company through which the Company raises at least \$1,500,000 in equity or debt financing, the CEO shall be granted a five-year warrant to purchase 224,490 shares (post reverse-split) of the Company's common stock.

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IR BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY  
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2. Related-Party Transactions, continued:

CONSULTING AGREEMENTS

On December 16, 2002, the Company entered into consulting agreements (the "Consulting Agreements") with its two founders and chief research scientists (the "Consultants"). The Consulting Agreements are on a month-to-month basis. Under the terms of the Consulting Agreements, the Consultants agree to place at the disposal of the Company their judgment and expertise in the area of acute lung injury. In consideration for these services, the Company agrees to pay each consultant a non-refundable fee of \$5,000 per month, which shall accrue until such time as the Company raises at least \$2,000,000 in equity or debt financing, at which time such accrued amount will become due and payable. As of December 31, 2003 and 2002, the Company has accrued payables due to the founders of \$125,000 and \$5,000, respectively.

PROPRIETARY RIGHTS AGREEMENT

In December 2002, the Company entered into a royalty-free license agreement (the "License Agreement") with its two founders and largest shareholders (the "Licensors"). Under the terms of the License Agreement, the Licensors grant to the Company an exclusive license to use and sublicense certain patents, medical applications, and other technologies developed by the Licensors. The Company's obligations under the License Agreement include (i) reasonable efforts to protect any licensed patents or other associated property rights; (ii) reasonable efforts to maintain confidentiality of any proprietary information; (iii) upon the granting by the U. S. Food and Drug Administration to the Company the right to market a product, the Company will maintain a broad form general liability and product liability insurance. The Company has recorded a capital contribution of \$9,250 and an offsetting intangible asset as a result of this agreement at December 31, 2002. It is being amortized over the 10-year term of the agreement.

DUE TO RELATED PARTIES

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Pursuant to the Consulting Agreements, during the period from October 30, 2002 (inception) to December 31, 2002, the Company accrued \$5,000 in consulting fees. During the period from January 1, 2003 to December 31, 2003, the Company accrued an additional \$120,000 in consulting fees. As of December 31, 2003 and 2002, the Company has accrued payables due to the founders of \$125,000 and \$5,000, respectively.

### OFFICE LEASE

The Company entered into a lease agreement for the period from December 1, 2002 to August 31, 2004. Rent expense is \$2,734 per month. The Company subleases its office space from Foresight Capital Partners, a company controlled by the Company'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. The remaining amount due under the non-cancelable lease agreement entered into December 1, 2002 is \$21,872 for the period January 1, 2004 through August 31, 2004.

Rent expense amounted to \$31,369 for the year ended December 31, 2003 and \$2,734 and \$34,103 for the periods from October 30, 2002 (inception) through December 31, 2002 and 2003, respectively.

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IR BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY  
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## 2. Related-Party Transactions, continued:

### InOne CONTRACT

The Company has entered into a series of contracts with InOne Advertising & Design, Inc. ("InOne"). InOne employs the spouse of the Company's Chief Executive Officer. These contracts include (i) a three-year agreement dated January 13, 2003 whereby InOne will design and create certain corporate identity and marketing materials in exchange for 36,000 shares (pre-split) of the Company's common stock and \$15,000. This agreement also provides that InOne will bill the Company on an hourly basis for additional services, as well as a \$100,000 termination fee if the agreement is terminated as a result of a merger or acquisition of the Company; (ii) an agreement dated March 14, 2003 whereby InOne will design, create, maintain, and host the Company's website for one year in exchange for 70,000 shares (pre-split) of the Company's common stock and \$4,200; (iii) an agreement dated December 30, 2003 whereby InOne will name and design a logo for the Company's new product for SARS application in exchange for \$5,000 and a warrant to purchase 10,000 shares of the Company's common stock at a price of \$0.25; (iv) an agreement dated December 31, 2003 whereby InOne will name and design a logo for the Company's new product for ARDS application in exchange for \$5,000 and a warrant to purchase 10,000 shares of the Company's common stock at a price of \$0.25.

### NOTES PAYABLE

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In October 2003, the Company was loaned \$30,000 by the father of one of the Company's founders. Pursuant to the terms of this transaction, the Company provided this lender with a warrant to purchase 15,000 shares of the Company's common stock at a price of \$2.00 per share. See Note 4 Notes Payable - Fourth Quarter Secured Convertible Promissory Notes.

In October 2003, the Company was loaned \$40,000 by a company controlled by the Company's President and CEO. Pursuant to the terms of this transaction, the Company provided this lender with a warrant to purchase 20,000 shares of the Company's common stock at a price of \$2.00 per share. See Note 4 Notes Payable - Fourth Quarter Secured Convertible Promissory Notes.

In December 2003, the Company was loaned \$20,000 by the mother-in-law of the Company's President and CEO. Pursuant to the terms of this transaction, the Company provided this lender with a warrant to purchase 10,000 shares of the Company's common stock at a price of \$2.00 per share. See Note 4 Notes Payable - Fourth Quarter Secured Convertible Promissory Notes.

### 3. Commitments and Contingencies:

#### MINIMUM FEE - ADVERTISING AND DESIGN

The Company has a three-year contract for the period January 2003 to January 2006 with its advertising and design agency. This contract stipulates that there will be a minimum guaranteed annual fee for consultation, planning, creative and account service of \$100,000 for each of the three years of the contract if termination of the contract is the result of a merger or acquisition of the Company. The contract was not terminated upon the GPN Merger Agreement.

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 these amounts.

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IR BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY  
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### 3. Commitments and Contingencies, continued:

#### OFFICE LEASE

The Company entered into a lease agreement for the period from December 1, 2002 to August 31, 2004. Rent expense is \$2,734 per month. The Company subleases its office space from Foresight Capital Partners, a company controlled by the Company'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. The remaining amount due under the non-cancelable lease agreement entered into

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December 1, 2002 is \$21,872 for the period January 1, 2004 through August 31, 2004.

Rent expense amounted to \$31,369 for the year ended December 31, 2003 and \$2,734 and \$34,103 for the periods from October 30, 2002 (inception) through December 31, 2002 and 2003, respectively.

### InOne CONTRACT

The Company has entered into a series of contracts with InOne Advertising & Design, Inc. ("InOne"). InOne employs the spouse of the Company's Chief Executive Officer. These contracts include (i) a three-year agreement dated January 13, 2003 whereby InOne will design and create certain corporate identity and marketing materials in exchange for 36,000 shares (pre-split) of the Company's common stock and \$15,000. This agreement also provides that InOne will bill the Company on an hourly basis for additional services, as well as a \$100,000 termination fee if the agreement is terminated as a result of a merger or acquisition of the Company; (ii) an agreement dated March 14, 2003 whereby InOne will design, create, maintain, and host the Company's website for one year in exchange for 70,000 shares (pre-split) of the Company's common stock and \$4,200; (iii) an agreement dated December 30, 2003 whereby InOne will name and design a logo for the Company's new product for SARS application in exchange for \$5,000 and a warrant to purchase 10,000 shares of the Company's common stock at a price of \$0.25; (iv) an agreement dated December 31, 2003 whereby InOne will name and design a logo for the Company's new product for ARDS application in exchange for \$5,000 and a warrant to purchase 10,000 shares of the Company's common stock at a price of \$0.25.

#### 4. Convertible Notes:

A summary of convertible promissory notes payable at December 31, 2003 is as follows:

Convertible Promissory Note	\$ 15,000
Secured Convertible Promissory Notes	245,000
Debt discount - value attributable to warrants issued with Amended Notes, net of accumulated amortization of \$84,169	(105,768)
Fourth Quarter Secured Convertible Promissory Notes	391,000
Debt Discount - value attributable to Company Warrants issued with Fourth Quarter Notes, net of accumulated amortization of \$84,882	(122,575)
Debt Discount - value attributable to Founders Warrants issued with Fourth Quarter Notes, net of accumulated amortization of \$72,691	(110,852)
	-----
	\$ 311,805
	=====

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IR BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY  
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#### 4. Convertible Notes, continued:

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### CONVERTIBLE PROMISSORY NOTE

On November 1, 2002, the Company received a loan in the amount of \$15,000. On January 20, 2003, a convertible promissory note agreement (the "Convertible Note") was executed in support of this loan. The Convertible Note is due on January 20, 2004, and bears interest at the rate of 8%. The Convertible Note is accelerated if certain events occur with regard to a sale of the Company's assets or an initial public offering of the Company's securities. The Convertible Note may be converted into shares of the Company's common stock at any time prior to the anniversary of the note by mutual consent of the Company and the note holder at the conversion price of \$1.67 per share. As additional consideration, the note holder also received a warrant to purchase 13,469 shares (post reverse-split) of the Company's common stock at the price of \$1.67 per share. In accordance with Emerging Issues Task Force Issue 98-5, ACCOUNTING FOR CONVERTIBLE SECURITIES WITH BENEFICIAL CONVERSION FEATURES OR CONTINGENTLY ADJUSTABLE CONVERSION RATIOS ("EITF 98-5"), the Company determined that the Convertible Note does not contain a beneficial conversion feature. The Company accounted for the warrant issued with the Convertible Promissory Note in accordance with Emerging Issues Task Force Issue 00-27, APPLICATION OF ISSUE NO. 98-5 TO CERTAIN CONVERTIBLE INSTRUMENTS ("EITF 00-27") and calculated the value of the warrant utilizing the Black-Scholes model and determined that the warrant had no value.

In May 2004, the Company received an extension of the terms of the Convertible Promissory Note to August, 2004.

### SECURED CONVERTIBLE PROMISSORY NOTES

In May and June 2003, the Company entered into eight note agreements (the "Secured Convertible Promissory Notes") in the aggregate principal amount of \$495,000. These notes were due 120 days from the date of issuance and were immediately convertible into shares of common stock at the option of the note holder. Notes aggregating a principal amount of \$295,000 carried interest at the rate of 10% per annum, and one note in the amount of \$200,000 carried a flat fee of 20% or \$40,000. Following the guidance in EITF 00-27, the Company computed the value of the beneficial conversion feature of the Convertible Secured Promissory Notes and recorded the amount of \$60,560 as a discount to notes payable and as additional paid-in capital during the twelve months ended December 31, 2003. This discount was amortized over the term of the notes, or 120 days.

As an additional incentive to investors in the Secured Convertible Promissory Notes, the Company also provided five-year warrants (the "Secured Note Warrants") to purchase that number of shares of common stock equal to one-half the initial principal amount of the Secured Convertible Promissory Notes. For example, an investor who purchased a \$10,000 Secured Convertible Promissory Note would receive a warrant to purchase 5,000 shares of common stock. The exercise price of the Secured Note Warrants is equal to the price per share paid by investors in a future equity financing (the "Reorganization Financing"). The Secured Note Warrants are not considered granted until the completion of the Reorganization Financing. Warrants to purchase a total of 247,500 shares of common stock are potentially issuable under the Secured Note Warrants. In accordance with EITF 00-27, because the Reorganization Financing had not occurred at December 31, 2003, the Company ascribed no value to the Secured Note Warrants at December 31, 2003.

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At December 31, 2003, three of the Secured Convertible Promissory Notes with an aggregate principal amount of \$250,000 and accrued interest of \$41,696 had been repaid. The remaining five notes with an aggregate principal amount of \$245,000 were exchanged for new notes (see "Amended Secured Convertible Promissory Notes").

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4. Convertible Notes, continued:

AMENDED SECURED CONVERTIBLE PROMISSORY NOTES

When the eight Secured Convertible Promissory Notes became due, three were paid and five were exchanged for new notes in October, 2003 (the "Amended Secured Convertible Promissory Notes", or the "Amended Notes"). The five Amended Notes have an aggregate principal amount of \$245,000 and bear interest at the rate of 8% per annum. The Amended Notes are convertible into common stock at a price of 60% of the price of common stock issued in a "Qualified Financing", defined for this purpose as the next sale of shares of capital stock of the Company within the term of the Amended Notes in one transaction or a series of transactions of at least \$500,000. The Company accounted for the Amended Notes in accordance with EITF 00-27 and accordingly, because the conversion of the Amended Notes is contingent upon a future event, the value of the Beneficial Conversion Feature associated with the Amended Notes will not be recorded until the occurrence of the Qualified Financing.

The common stock underlying the Amended Secured Convertible Promissory Notes is subject to demand registration rights whereby, should the Company receive a request by holders of at least 30% of the total number of shares underlying the Amended Notes, the Company is obligated to file a registration statement within 90 days of such request. The Amended Notes are secured by substantially all the assets of the Company.

The investors in the Amended Notes also received five-year warrants (the "Amended Note Warrants") to purchase the number of shares of common stock equal to one-half the principal amount of their investment in the Amended Notes. For example, an investor who purchased an Amended Note in the amount of \$10,000 would also receive a warrant to purchase 5,000 shares of the Company's common stock. The exercise price of the Amended Note Warrants is \$2.00.

The total number of shares of common stock potentially issuable pursuant to the Amended Note Warrants is 122,500. See note 6.

In accordance with EITF 00-27, the Company recognized the value attributable to the Amended Note Warrants in the amount of \$189,937 to additional paid-in capital and a discount against the Amended Notes.

The Company valued the Amended Note Warrants using the Black-Scholes

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pricing model and the following assumptions:

- o contractual terms of 5 years
- o an average risk free interest rate of 2.375%
- o a dividend yield of 0.00%
- o volatility of 312%
- o debt discount attributed to the value of the warrants issued is amortized over the 180 day term of the Amended Notes as interest expense.

During the twelve months ended December 31, 2003, the Company amortized \$84,169 of the discount associated with the Amended Notes to interest expense.

The common stock underlying the Amended Notes is subject to demand registration rights whereby, should the Company receive a request by holders of at least 30% of the total number of shares underlying the Amended Notes, the Company is obligated to file a registration statement within 90 days of such request. The Amended Notes are secured by substantially all the assets of the Company .

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4. Convertible Notes, continued:

In May 2004, the Company received 90 day extensions of the terms of the Amended Convertible Promissory Note to July, 2004.

FOURTH QUARTER SECURED CONVERTIBLE PROMISSORY NOTES

During October, November, and December 2003, the Company entered into ten note agreements in the aggregate amount of \$391,000 (the "Fourth Quarter Secured convertible Promissory Notes", or the "Fourth Quarter Notes"). The Fourth Quarter Notes bear interest at the rate of 8% per annum and have a term of 180 days, and are convertible into common stock at a price equal to 80% of the price per share of common stock issued in the Qualified Financing. The Company accounted for the Fourth Quarter Notes in accordance with EITF 00-27 and accordingly, because the conversion of the Amended Notes is contingent upon a future event, the value of the BCF associated with the Fourth Quarter Notes will not be recorded until the occurrence of the Qualified Financing.

The ten investors in the Fourth Quarter Notes also received five-year warrants (the "Fourth Quarter Company Warrants") to purchase the number of shares of common stock equal to 50% of the principal amount of their investment in the Fourth Quarter Notes. For example, an investor who purchased a Fourth Quarter Note in the amount of \$10,000 would received a warrant to purchase 5,000 shares of the Company's common stock. The exercise price of the Fourth Quarter Note Warrants is \$2.00. The total number of shares of common stock issuable pursuant to the Fourth Quarter Note Warrants is 195,500. See note 6.

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In accordance with EITF 00-27, the Company recorded the value attributable to the Fourth Quarter Company Warrants in the amount of \$207,457 to additional paid-in capital and a discount against the Fourth Quarter Notes. The Company valued the Fourth Quarter Company Warrants in accordance with EITF 00-27 using the Black-Scholes pricing model and the following assumptions:

- o contractual terms of 5 years
- o an average risk free interest rate of 2.375%
- o a dividend yield of 0.00%
- o volatility of 312%
- o debt discount attributed to the value of the warrants issued is amortized over the 180 day term of the Amended Notes as interest expense.

During the twelve months ended December 31, 2003, the Company amortized \$84,882 of the discount associated with the Fourth Quarter Company Warrants to interest expense.

Nine of the ten investors who received a Fourth Quarter Note Warrant also received a five-year warrant (the "Fourth Quarter Founders Warrants") from two of the Company's founders (the "Founders") to purchase directly from the Founders at a price of \$0.01 per share the number of shares of common stock equal to 50% of their investment in the Fourth Quarter Notes. For example, an investor who purchased a Fourth Quarter Note in the amount of \$10,000 would have received a warrant to purchase 5,000 shares of the Company's common stock directly from the Founders. The total number of shares of common stock issuable pursuant to the Fourth Quarter Note Warrants is 183,000. The Fourth Quarter Founders Warrants are not an obligation of the Company. However, they are considered a capital contribution by the Founders and are recorded as a discount to the Fourth Quarter Notes and as an addition to additional paid-in capital during the twelve months ended December 31, 2003 in the amount of \$183,543.

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4. Convertible Notes, continued:

FOURTH QUARTER SECURED CONVERTIBLE PROMISSORY NOTES (CONTINUED)

The Company valued the warrants in accordance with EITF 00-27 using the Black-Scholes pricing model and the following assumptions:

- o contractual terms of 5 years
- o an average risk free interest rate of 2.375%
- o a dividend yield of 0.00%
- o volatility of 312%
- o debt discount attributed to the value of the warrants issued is amortized over the 180 day term of the Amended Notes as interest expense.



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During the twelve months ended December 31, 2003, the Company amortized \$72,691 of the discount associated with the Fourth Quarter Founders Warrants to interest expense.

The total discount against the Fourth Quarter Notes (attributable to both the Founders Warrants and the Company Warrants) was \$391,000. Of this amount, a total of \$157,573 was charged to interest expense during the twelve months ended December 31, 2003.

In May 2004, the Company received a 90 day extension of the terms of the Amended Convertible Promissory Notes to July, August, and September, 2004.

5. Notes Payable - Shareholder:

At December 31, 2003, the Company has outstanding two notes payable to shareholders in the aggregate amount of \$62,171. These notes bear interest at the rate of 6% per annum, which is capitalized quarterly.

6. Stockholders' Deficit:

PREFERRED STOCK

The Company is authorized to issue 10,000,000 shares of preferred stock, par value \$0.001 per share. No shares of preferred stock have been issued as of December 31, 2003.

COMMON STOCK

The Company is authorized to issue 100,000,000 shares of common stock, par value \$0.001 per share.

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

Also in December 2002, the Company issued 702,655 shares (post reverse-split) 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 (post reverse-split) of common stock with a fair value of \$9,000 to a vendor for services rendered.

In December 2002, the Company sold 92,789 shares (post reverse-split) of its common stock for net proceeds of \$31,001.

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6. Stockholders' Deficit, continued:

During January 2003, the Company issued 49,388 shares (post

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reverse-split) of its common stock with a fair value of \$13,750 to 2 service providers.

### COMMON STOCK (CONTINUED)

During January 2003, the Company sold 164,776 (post reverse-split) shares of its common stock for \$50,000 in cash.

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

In April 2003, the Company converted a note payable in the amount of \$200,000 to 718,368 shares (post reverse-split) of its common stock.

In April 2003, the Company issued 7,184 shares (post reverse-split) of its common stock with a fair value of \$2,030 to a service provider.

In May 2003, the Company sold 8,980 shares (post reverse-split) of its common stock for \$5,000 in cash.

In June 2003, the Company sold 17,959 shares (post reverse-split) of its common stock for \$10,000 in cash.

In June 2003, the Company converted a note in the amount of \$100,000 into 359,184 shares (post reverse-split) of common stock.

In July 2003, the Company issued 1,184,065 shares (post reverse-split) of its common stock pursuant to the Merger with GPN Network, Inc.

### WARRANTS

At December 31, 2002, the Company had outstanding warrants to purchase 13,469 shares of common stock at \$1.67 per share.

During the twelve months ended December 31, 2003, the Company issued warrants to purchase 84,786 shares (post reverse-split) of common stock at prices ranging from \$0.25 to \$2.00 per share to eight service providers. The Company valued the warrants using the Black-Scholes calculation model, and the warrants were deemed to have a combined value of \$85,860. This amount was charged to expense on the Company's financial statements for the twelve months ending December 31, 2003.

In October 2003, pursuant to the Amended Note agreements (see note 4), the Company issued the Amended Note Warrants to purchase 122,500 shares of its common stock at a price of \$2.00 per share. The Company valued the Amended Note Warrants using the Black-Scholes calculation model, and the warrants were deemed to have a combined value of \$189,937. This amount was recorded as a discount to the Amended Notes and an addition to paid-in capital, and is being charged to expense over the term of the notes, or 180 days. During the twelve months ended December 31, 2003, the Company recognized \$84,169 of expense in relation to these warrants.

In October, November, and December 2003, pursuant to the Fourth Quarter Note agreements (see note 4), the Company issued the Fourth Quarter Company Warrants to purchase 195,500 shares of its common stock at a price of \$2.00 per share. In addition, also pursuant to the Fourth Quarter Note agreements, two of the Company's founders issued directly to investors in the Fourth Quarter Notes warrants to purchase directly

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6. Stockholders' Deficit, continued:

from the founders a total of 183,000 shares of the Company's common stock at a price of \$0.01 per share. The Founders Warrants are recorded as a capital contribution to the Company. The Company valued the Company Warrants and the Founders Warrants using the Black-Scholes valuation model. The combined value of the Company Warrants and the Founders Warrants exceeded the total principal amount of the Fourth Quarter Notes, or \$391,000. The Company allocated the relative value of the Founders Warrants and the Company Warrants to the total value of the Fourth Quarter Notes, or \$391,000, and recorded this amount as a discount to the Fourth Quarter Notes and as an addition to paid-in capital. The discount is being amortized over the life of the notes, or 180 days. During the twelve months ended December 31, 2003, the Company recognized \$157,573 of expense in relation to these warrants.

The following represents a summary of warrant transactions:

	Warrants Outstanding	Weighted Average Exercise Price
	-----	-----
Balance, December 31, 2001	0	0
Granted	13,469	\$0.84
Exercised	0	0
	-----	-----
Balance, December 31, 2002	13,469	\$0.84
Granted	402,786	\$1.78
Exercised	0	0
	-----	-----
Balance, December 31, 2003	416,255	\$1.78
	=====	=====

REVERSE STOCK SPLIT

On June 30, 2003, the Company's Board of Directors approved a 0.897960946 for 1.00 reverse-split of the Company's common stock. Immediately before the reverse-split, there were 11,728,333 shares of the Company's common stock issued and outstanding; immediately after the split, there were 10,531,585 shares of the Company's common stock issued and outstanding. The effect of the reverse split has been presented in the accompanying financial statement and footnote disclosures.

7. Stock Option Plan:

During the twelve months ended December 31, 2003, the Company adopted the 2003 Stock Option, Deferred Stock and Restricted Stock Plan (the "Plan") which authorizes the Board of Directors in accordance with the terms of the Plan, among other things, to grant incentive stock options, as defined by Section 422(b) of the Internal Revenue Code,

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nonstatutory stock options (collectively, the "Stock Options") and awards of restricted stock and deferred stock and to sell shares of common stock of the Company ("Common Stock") pursuant to the exercise of such stock options for up to an aggregate of 3,232,658 shares. The options will have a term not to exceed ten years from the date of the grant.

The Company has elected to follow APB Opinion No. 25 (Accounting for Stock Issued to Employees) in accounting for its employee stock options. Accordingly, no compensation expense is recognized in the Company's financial statements related to options issued to employees because the exercise price of the Company's employee stock options equals the market price of the Company's common stock on the date of grant. For options issued to consultants, pursuant to Financial Accounting Standards Board Statement No. 123 (Accounting for Stock-Based Compensation) the Company determined that there was no compensation costs based on the fair value at the grant date for its stock options.

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7. Stock Option Plan, continued:

The Company had not issued any stock options under the Plan at December 31, 2003.

Through December 31, 2002, GPN had granted, pre-Merger, stock options to certain employees and consultants which are exercisable over various periods through March 2010. These stock options are currently held by the Company outside of the Plan. A summary of the Company's stock options granted outside the Plan as of December 31, 2003 and 2002 is presented below:

	2003 ----	Average Exercise Price	2002 ----	Average Exercise Price
	Options		Options	
Outstanding at beginning of period	0	N/A	30,606	\$ 50.00
Granted or assumed from GPN	31,606	\$50.00	0	
Exercised	0	N/A	0	
Cancelled	0	N/A	0	
Outstanding at end of year	31,606	\$ 50.00	30,606	\$ 50.00
Weighted-average value of options granted during the period	\$ N/A		\$ N/A	

8. Private Placement Agreement (Reorganization Financing) and Offering Memorandum:

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On May 28, 2003, the Company entered into an engagement agreement (the "Private Placement Agreement") with VMR Capital Markets, U.S. ("VMR") whereby VMR will act as the agent for the Company in connection with the private placement of up to \$2,000,000 of the Company's common stock on a best efforts basis. The offering will be made only to "Qualified Institutional Buyers" and individuals who are "Accredited Investors," as those terms are defined in Rule 144 and in Regulation D, respectively, under the Securities Act of 1933, as amended. The term of the Private Placement Agreement is for a period of six months. Upon consummation of a financing under the Private Placement Agreement, the Company will pay to VMR a fee equal to 10% of the principal amount of any common stock sold in the Private Placement. In addition, the Company will pay to VMR a non-accountable expense allowance equal to 3% of the principal amount of stock sold in the Private Placement. For the year ended December 31, 2003, the Company had charged \$90,000 to operations. On November 28, 2003, the Private Placement Agreement expired and no funds had been raised.

### 9. Income Taxes

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

At December 31, 2003, the Company has available for federal income tax purposes a net operating loss carryforward of approximately \$ 1,900,000, expiring in the year 2023, that may be used to offset future taxable income. The Company has provided a valuation reserve against the full amount of the net operating loss benefit, since in the opinion of management based upon the earnings history of the Company, it is more likely than not that the benefits will not be realized. Due to significant changes in the Company's ownership, the future use of its existing net operating losses may be limited.

Components of deferred tax assets as of December 31, 2003 are as follows:

Non Current:	
Net operating loss carryforward	\$ 650,000
Valuation allowance	(650,000)
	-----
Net deferred tax asset	\$ -
	=====

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### 10. Development Stage Company:

The Company is in the development stage, and its operations are subject to the risks inherent in the establishment of a new business with previously untested technology. The Company has generated no revenues and has accumulated losses of more than \$1.9 million for the period from inception (October 30, 2002) to December 31, 2003. Since

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inception, the Company has financed its operations primarily by the issuance of equity securities and short-term borrowings.

During 2003, the Company financed its operations with (i) sale of equity securities of \$65,000 and (ii) short-term borrowings of \$1,186,000. See Notes 4 and 5.

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

11. Subsequent Events:

FINANCIAL PUBLIC RELATIONS

In January 2004, the Company signed a six-month agreement with a consultant for financial public relations services in exchange for a monthly fee of \$6,000 and a warrant to purchase 50,000 shares of the Company's common stock at a price equal to the closing price of the Company's common stock on the date of the agreement.

12% SENIOR SECURED PROMISSORY NOTE

In January 2004, the Company received a loan in the amount of \$150,000 (the "January Note"). The January Note bears interest at the rate of 12% and has a term of 90 days. The January Note also provides that the lender receives 600,000 shares of the Company's common stock.

In April 2004, the Company purchased the January Note and replaced it with a new note (the "April Note"). The April Note bears interest at the rate of 12% per annum and has a term of 90 days. The April Note also provides that the lender receives 600,000 shares of the Company's common stock.

MARKETING AGREEMENTS

In January and March 2004, the Company entered into two one-year agreements with marketing consultants (the "Marketing Consultants") for services relating to marketing the company with investors and the investment community. The Company agreed to compensate the Marketing Consultants with an aggregate of 1,851,600 shares of the Company's common stock.

S-8 REGISTRATION

In March 2004, the Company completed an S-8 Registration Statement with the Securities and Exchange Commission to register 1,800,000 shares of its common stock.

STOCK COMPENSATION

In February, March, and April 2004, the Company issued 206,100 shares of common stock to seven service providers.

In April 2004, the Company issued 200,000 shares of common stock and a five-year warrant to purchase 10,000 shares of common stock at a price

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of \$1.00 per share to its Chief Financial Officer for services.

In April 2004, the Company issued 62,500 shares of common stock to its operations manager for services.

In April 2004, the Company issued 20,000 shares of common stock to a service provider.

### STRATEGIC PLANNING CONSULTING AGREEMENT

In March 2004, the Company entered into a six month agreement with a consultant for services relating to strategic planning, marketing, operations, and business development in exchange for 250,000 shares of the Company's common stock.

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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

### STOCK SPLIT

In April 2004, the Company effected a two-for-one forward split of its common stock. The effect of this stock has not been presented in the accompanying financial statements and footnote disclosures.

### CORPORATE PLANNING CONSULTING AGREEMENT

In April 2004, the Company entered into a twelve-month consulting agreement for corporate planning services in exchange for 600,000 shares of the Company's common stock and a warrant to purchase 750,000 shares of common stock at \$2.00 per share and a warrant to purchase 250,000 shares of common stock at \$3.00 per share.

### NOTES PAYABLE EXTENSION:

In May 2004, the Company negotiated 90 day extensions of its maturing notes payable.

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

On April 21, 2004, the Company terminated its relationship with Stonefield Josephson, Inc. and engaged Russell Bedford Stefanou Merchandani, LLP as the Company's independent certified public accountants. The decision to change accountants was approved by the Company's Board of Directors. Stonefield Josephson's report on the consolidated financial statements of ImmuneRegen BioSciences, Inc. for the year ended December 31, 2002 did not contain an adverse opinion or a disclaimer of opinion and was not modified or qualified as to uncertainty, audit scope or accounting principles; however, such report contained an explanatory paragraph relating to substantial doubt regarding the

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uncertainty of the Company's ability to continue as a going concern.

On July 15, 2003, GPN terminated its relationship with Singer Lewak Greenbaum & Goldstein as the Company's independent certified public accountants and engaged Stonefield Josephson, Inc. The decision to change accountants was approved by the Company's Board of Directors. Singer Lewak Greenbaum & Goldstein's report on the consolidated financial statements for the year ended December 31, 2002 did not contain an adverse opinion or a disclaimer of opinion and was not modified or qualified as to uncertainty, audit scope or accounting principles; however, such report contained an explanatory paragraph relating to substantial doubt regarding the uncertainty of the Company's ability to continue as a going concern.

On January 1, 2002, the Company engaged Singer Lewak Greenbaum & Goldstein LLP as its new independent accountants. Such engagement was approved by the Company's Board of Directors. In the Company's two most recent fiscal years and any subsequent interim period to the date of engagement, the Company has not consulted with Singer Lewak Greenbaum & Goldstein LLP regarding either: (i) the application of accounting principles to a specified transaction, either completed or proposed; or the type of audit opinion that might be rendered on the Company's financial statements, and neither a written report was provided to the Company nor oral advice was provided that Singer Lewak Greenbaum & Goldstein LLP concluded was an important factor considered by the Company in reaching a decision as to the accounting, auditing or financial reporting issue; or (ii) any matter that was either the subject of a disagreement or event, as those terms are used in Item 304(a)(1)(iv) of Regulation S-B and the related instructions to Item 304 of Regulation S-B.

### ITEM 8A. CONTROLS AND PROCEDURES.

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

Evaluation of disclosure and controls and procedures. As of the end of the period covered by this Annual Report, we conducted an evaluation, under the supervision and with the participation of our chief executive officer and chief financial officer, of our disclosure controls and procedures (as defined in Rules 13a-15(e) of the Exchange Act). Based on this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

Changes in internal controls over financial reporting. There was no change in our internal controls, which are included within disclosure controls and procedures, during our most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls.

### PART III

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



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Executive officers are elected annually by the Board of Directors. Board members serve one-year terms until their death, resignation or removal by the Board of Directors.

NAME	AGE	POSITION
Michael K. Wilhelm	36	Chief Executive Officer and Director
Mark L. Witten, Ph.D.	50	Director and Research Scientist
David T. Harris, Ph.D.	47	Director and Research Scientist
Theodore E. Staahl, M.D.	59	Director

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NAME	AGE	POSITION
Eric J. Hopkins	49	Chief Financial Officer
Steven J. Scronic	31	Secretary

MICHAEL K. WILHELM, PRESIDENT, CHIEF EXECUTIVE OFFICER AND DIRECTOR. Mr. Wilhelm has served as our President and Chief Executive Officer and on our Board of Directors since July 2003 and as President and Chief Executive Officer of ImmuneRegen BioSciences, Inc. since December 2002 and on its Board of Directors since November 2002. Mr. Wilhelm has been actively involved in the financial industry since 1990. After leaving the brokerage industry, Mr. Wilhelm founded Foresight Capital Partners in July 1996, a company designed to identify early stage companies with above average growth potential and assist them in reaching the next stage of development. In working with these companies, Mr. Wilhelm took an active role, provided advisory services and facilitated financing for continued growth and development. Mr. Wilhelm was Managing Director of Foresight Capital Partners until December 2002.

MARK L. WITTEN, PH.D., DIRECTOR AND RESEARCH SCIENTIST. Dr. Witten has served as a research scientist for our company and on our Board of Directors since July 2003 and as a research scientist for ImmuneRegen BioSciences, Inc. since December 2002 and on its Board of Directors since November 2002. Dr. Witten has served as a Research Professor at the University of Arizona since July 2000. Since July 1998 Dr. Witten has served as the Director of the Joan B. and Donald R. Diamond Lung Injury Laboratory in the Department of Pediatrics at the University of Arizona College of Medicine. Dr. Witten obtained his Ph.D. from Indiana University in 1983 with a double major in physiology and exercise physiology. He conducted a post-doctoral fellowship in Respiratory Sciences at the University of Arizona College of Medicine from 1983 to 1988. He then spent two years as an Assistant Biologist at Massachusetts General Hospital and Instructor in Medicine at Harvard Medical School. He returned to The University of Arizona College of Medicine in 1990. Dr. Witten has authored over 200 published manuscripts, book chapters and abstracts.

DAVID T. HARRIS, PH.D., DIRECTOR AND RESEARCH SCIENTIST. Dr. Harris is a Professor in the Department of Microbiology and Immunology in the College of Medicine at The University of Arizona. Dr. Harris obtained his Ph.D. degree from Wake Forest University in 1982 with a major in microbiology and immunology. After three years of post-doctoral fellowship (1982-1985) in immunology at the Ludwig Institute for Cancer Research in Lausanne, Switzerland, Dr. Harris became a Research Assistant Professor in the College of Medicine at the University of North Carolina-Chapel Hill. In 1989, Dr. Harris moved to The University of Arizona College of Medicine. Dr. Harris is also Director of the Stem Cell Bank and Chief Science Officer for Cord Blood Registry, Inc. He is also Head of the

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Gene Therapy Group. Dr. Harris is a co-inventor with Dr. Witten on the substance P patents and also holds three additional U.S. patents. Dr. Harris has authored more than 200 published papers, book chapters and abstracts. Dr. Harris has extensive experience in start-up biotechnology companies, having established one of the first stem cell banks in 1992 at the University of Arizona. Additionally, Dr. Harris has extensively consulted for a number of biotechnology companies.

THEODORE E. STAAHL, M.D., DIRECTOR. Dr. Staahl founded the Cosmetic, Plastic and Reconstructive Surgery Center in 1978. Dr. Staahl's professional training was received at the University of Illinois and the University of Wisconsin and is board certified by the American Board of Facial, Plastic and Reconstruction Surgeons, the Board of Cosmetic Surgeons and the American Board of Head and Neck Surgeons. Dr. Staahl has presented papers at national and international meetings on hair transplant, rhinoplasty and cleft lip deformities. Additionally, Dr. Staahl is currently participating in the FDA approval process of another biotechnology company.

ERIC HOPKINS, CHIEF FINANCIAL OFFICER. Mr. Hopkins is a certified public accountant and financial consultant located in Aliso Viejo, California. From April 2001 to the present, Mr. Hopkins has been in private practice, specializing in financial consulting to publicly held companies. He is also President of EdgarEyes, LLC, a financial reporting firm. From April 2000 to April 2001, Mr. Hopkins served as the Chief Financial Officer of the Registrant. From July 1997 to April 2000, he served as Director of Finance for Unisys-PulsePoint Communications, a telecommunications hardware/software company located in Carpinteria, California. Mr. Hopkins obtained his MBA from Pepperdine University.

STEVEN J. SCRONIC, SECRETARY. Mr. Scronic has worked in the investment banking sector of the financial services industry since 1993, specializing in public financings and private placements, including institutional 144 and non-arbitrage Regulation D private placements of debt and equity for private and public companies. His corporate finance experience has focused on generating,

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analyzing, structuring and placing middle-market based financial transactions. Previously, Mr. Scronic was a Vice President of WestPark Capital and an equity analyst and investment banker for John Charles & Associates, Inc. and EBI Securities, Inc. Mr. Scronic has been elected to several corporate boards and currently serves on the board of two public companies and several private companies.

Compliance With Section 16(A) of the Securities Exchange Act of 1934  
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Section 16(a) of the Securities Exchange Act of 1934 requires the Company's directors and executive officers and persons who own more than ten percent of a registered class of the Company's equity securities to file with the SEC initial reports of ownership and reports of changes in ownership of Common Stock and other equity securities of the Company. Officers, directors, and greater than ten percent stockholders are required by SEC regulations to furnish the Company with copies of all Section 16(a) forms they file. To the Company's knowledge, during the year ended December 31, 2001, all Section 16(a) filing requirements applicable to the Company's officers, directors and greater than ten percent stockholders were complied with.

ITEM 10. EXECUTIVE COMPENSATION

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### Summary Compensation Table

The following table sets forth information concerning all compensation awarded to, earned by, or paid to (1) our Chief Executive Officer and President, (2) our former Chief Executive Officer and President who served in such capacities until July 2003 when ImmuneRegen BioSciences, Inc. became a wholly-owned subsidiary of IR BioSciences, Inc. (the "Reorganization") and (3) each of the other executive officers whose annual salary and bonus during 2001, 2002 and 2003 exceeded \$100,000 (the "Named Executive Officers").

Name and Principal Position	Year	Annual Compensation	
		Salary (\$)	Bonus(\$)
Michael K. Wilhelm	2003	125,000	0
Chief Executive Officer	2002	5,208	0
and President(1).....	2001	0	0
Todd M. Ficeto			
Chief Executive Officer,	2003	0	0
Chief Financial Officer,	2002	0	0
President and Secretary(2).....	2001	0	0

(1) Michael K. Wilhelm has served as Chief Executive Officer and President of IR BioSciences Holdings, Inc. since July 2003 when the Reorganization was completed. Prior to the completion of the Reorganization, Mr. Wilhelm served as Chief Executive Officer and President of ImmuneRegen BioSciences, Inc. since December 2002. Mr. Wilhelm's compensation is reported in the table with respect to his positions at both IR BioSciences Holdings, Inc. and ImmuneRegen BioSciences, Inc. for the year ended December 31, 2003.

(2) Todd M. Ficeto served as Chief Financial Officer and Secretary of GPN Network, Inc. from July 2001 until the completion of the Reorganization in July 2003 and as Chief Executive Officer and President of GPN Network, Inc. from August 2001 until the completion of the Reorganization in July 2003.

### Option/sar Grants in Last Fiscal Year

None.

### Aggregate Option Exercised in Last Fiscal Year End Y/e Option Values

None.

### Stock Options

During the twelve months ended December 31, 2003, the Company adopted the 2003 Stock Option, Deferred Stock and Restricted Stock Plan (the "Plan") which authorizes the Board of Directors in accordance with the terms of the Plan, among other things, to grant incentive stock options, as defined by Section

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422(b) of the Internal Revenue Code, nonstatutory stock options (collectively, the "Stock Options") and awards of restricted stock and deferred stock and to sell shares of common stock of the Company ("Common Stock") pursuant to the exercise of such stock options for up to an aggregate of 1,800,000

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shares. The options will have a term not to exceed ten years from the date of the grant. The Company had not issued any stock options under the Plan at December 31, 2003.

Through December 31, 2002, GPN had granted, pre-Merger, stock options to certain employees and consultants which are exercisable over various periods through March 2010. These stock options are currently held by the Company outside of the Plan. A summary of the Company's stock options granted outside the Plan as of December 31, 2003 and 2002 is presented below:

The following summarizes the stock option transactions:

	2003 ----	Average Exercise Price	2002 ----
Options			Options
Outstanding at beginning of period	0	N/A	30,606
Assumed from GPN	31,606	\$ 50.00	0
Exercised	0	N/A	0
Cancelled	0	N/A	0
Outstanding at end of year	31,606	\$ 50.00	30,606
Weighted-average value of options granted during the period	\$ N/A		\$ N/A

There were no new option grants during the periods ending December 31, 2003 or 2002.

### Warrants

At November 2002, the Company issued a warrant to purchase 13,469 shares of common stock at \$1.67 per share pursuant to a note payable agreement.

During the twelve months ended December 31, 2003, the Company issued warrants to purchase 84,786 shares of common stock at prices ranging from \$0.25 to \$2.00 per share to eight service providers. The Company valued the warrants using the Black-Scholes calculation model, and the warrants were deemed to have a combined value of \$85,860. This amount was charged to expense on the Company's financial statements for the twelve months ending December 31, 2003.

In October 2003, pursuant to the Amended Note agreements (see note 4), the Company issued the Amended Note Warrants to purchase 122,500 shares of its common stock at a price of \$2.00 per share. The Company valued the Amended Note Warrants using the Black-Scholes calculation model, and the warrants were deemed to have a combined value of \$189,937. This amount was recorded as a discount to the Amended Notes and an addition to paid-in capital, and is being charged to expense over the term of the notes, or 180 days. During the twelve months ended December 31, 2003, the Company recognized \$84,169 of expense in relation to

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these warrants.

In October, November, and December 2003, pursuant to the Fourth Quarter Note agreements (see note 4), the Company issued the Fourth Quarter Company Warrants to purchase 195,500 shares of its common stock at a price of \$2.00 per share. In addition, also pursuant to the Fourth Quarter Note agreements, two of the Company's founders issued directly to investors in the Fourth Quarter Notes

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warrants to purchase directly from the Founders a total of 158,100 shares of the Company's common stock at a price of \$0.01 per share. The Founders Warrants are recorded as a capital contribution to the Company. The Company valued the Company Warrants and the Founders Warrants using the Black-Scholes valuation model. The combined value of the Company Warrants and the Founders Warrants exceeded the total principal amount of the Fourth Quarter Notes, or \$391,000. The Company allocated the relative value of the Founders Warrants and the Company Warrants to the total value of the Fourth Quarter Notes, or \$391,000, and recorded this amount as a discount to the Fourth Quarter Notes and as an addition to paid-in capital. The discount is being amortized over the life of the notes, or 180 days. During the twelve months ended December 31, 2003, the Company recognized \$157,573 of expense in relation to these warrants.

The following represents a summary of warrant transactions:

	Warrants Outstanding	Weighted Average Exercise Price
	-----	-----
Balance, December 31, 2001	0	0
Granted	13,469	\$0.84
Exercised	0	0
	-----	-----
Balance, December 31, 2002	13,469	\$0.84
Granted	402,786	\$1.78
Exercised	0	0
	-----	-----
Balance, December 31, 2003	416,255	\$1.78
	=====	=====

### ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information as of May 5, 2004, with respect to (i) all officers and directors, and greater than 5% owners of the Company's common stock.

Name	Beneficial Ownership	Percentage of Class
-----	-----	-----
Mark L. Witten	8,306,138 shares	30.1%
David T. Harris	8,306,138 shares	30.1%
Michael K. Wilhelm (1)	1,886,805 shares	6.7%
Eric J. Hopkins (2)	220,070 shares	0.8%
Theodore F. Staahl (3)	1,335,002 shares	4.7%
John J. Machado	1,766,289 shares	6.4%

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Directors and Officers as a Group      20,094,153 shares                      70.1%

- (1) Consists of (i) 1,406,805 shares of common stock, (ii) 400,000 shares issuable upon conversion of a note payable held by Mr. Wilhelm, and (iii) 80,000 shares issuable upon exercise of warrants.
- (2) Consists of (i) 200,070 shares of common stock and (ii) 22,000 shares issuable upon exercise of warrants.
- (3) Consists of (i) 808,165 shares of common stock, (ii) 350,000 shares issuable upon conversion of a note payable held by Mr. Staahl, and (iii) 176,837 shares issuable upon exercise of warrants.

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### ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

In October 2003, the Company was loaned \$30,000 by the father of one of the Company's founders. Pursuant to the terms of this transaction, the Company provided this lender with a warrant to purchase 15,000 shares of the Company's common stock at a price of \$2.00 per share.

In October 2003, the Company was loaned \$40,000 by a company controlled by the Company's President and CEO. Pursuant to the terms of this transaction, the Company provided this lender with a warrant to purchase 20,000 shares of the Company's common stock at a price of \$2.00 per share.

In December 2003, the Company was loaned \$20,000 by the mother-in-law of the Company's President and CEO. Pursuant to the terms of this transaction, the Company provided this lender with a warrant to purchase 10,000 shares of the Company's common stock at a price of \$2.00 per share.

### ITEM 13. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

- (a) Financial Statements, Financial Statement Schedules and Exhibits

Independent Auditor's Report.

Consolidated Balance Sheet as of December 31, 2003.

Consolidated Statements of Operations for the twelve months ended December 31, 2003 and from the date of inception (October 30, 2002) to December 31, 2003.

Consolidated Statement of Stockholder's Equity for the period from the date of inception (October 30, 2002) to December 31, 2003.

Consolidated Statements of Cash Flows for the twelve months ended December 31, 2003 and from the date of inception (October 30, 2002) to December 31, 2003.

Notes to Consolidated Financial Statements.

#### EXHIBITS

Exhibit Number	Description
-----	-----

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- 23.1 Consent of Stonefield Josephson, Inc.
- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbannes Oxley Act of 2002
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbannes Oxley Act of 2002
- 32.1\* Certification Pursuant To 18 U.S.C.ss.1350, As Adopted Pursuant To Section 906 Of The SARBANES-OXLEY ACT OF 2002
- 32.2\* Certification Pursuant To 18 U.S.C.ss.1350, As Adopted Pursuant To Section 906 Of The SARBANES-OXLEY ACT OF 2002

(b) Form 8K/A filed as of December 29, 2003 to amend the Company's form 8K filed on July 7, 2003 pursuant to a change in control of the Company.

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

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### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth fees billed to us by our auditors during the fiscal years ended December 31, 2003 and December 31, 2002 for: (i) services rendered for the audit of our annual financial statements and the review of our quarterly financial statements, (ii) services by our auditor that are reasonably related to the performance of the audit or review of our financial statements and that are not reported as Audit Fees, (iii) services rendered in connection with tax compliance, tax advice and tax planning, and (iv) all other fees for services rendered.

		December 31, 2003	December 31, 2002
		-----	-----
(i)	Audit Fees	\$ 49,676	\$ 30,000
(ii)	Audit Related Fees	\$ --	\$ --
(iii)	Tax Fees	\$ --	\$ --
(iv)	All Other Fees	\$ --	\$ --
		-----	-----
	Total fees	\$ 49,676	\$ 30,000
		=====	=====

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

**AUDIT-RELATED FEES.** Consists of fees billed for assurance and related services that are reasonably related to the performance of the audit or review of the Company's consolidated financial statements and are not reported under "Audit

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Fees." There were no Audit-Related services provided in fiscal 2003 or 2002.

TAX FEES. Consists of fees billed for professional services for tax compliance, tax advice and tax planning..

ALL OTHER FEES. Consists of fees for products and services other than the services reported above. There were no management consulting services provided in fiscal 2003 or 2002.

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

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on July 20, 2005

IR BioSciences Holdings, Inc.

By: /s/ Michael K. Wilhelm

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Michael K. Wilhelm  
President and Chief Executive Officer