IR BIOSCIENCES HOLDINGS INC
Form 10KSB
April 19, 2005

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

FORM 10-KSB

(X) Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2004.

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.)

4021 N. 75th Street, Suite 201, Scottsdale, AZ	85251
(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 or any amendment to this Form 10-KSB. [ ]

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

The aggregate market value of the Registrant's issued and outstanding shares of common stock held by non-affiliates of the Registrant as of April 3, 2005 (based on the average of the bid and asked prices as reported by the NASD OTC Bulletin Board as of that date) was approximately $20,377,554.

The number of shares outstanding of Registrant's Common Stock, par value $0.001 as of April 3, 2005: 70,074,188.

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

Transitional Small Business Disclosure Format Yes _____ No X _____

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FORWARD-LOOKING STATEMENTS

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

PART I

ITEM 1. DESCRIPTION OF BUSINESS

IR BioSciences Holdings, Inc., a development-stage biopharmaceutical company, is engaged in the research, development and commercialization of important life saving, health-enhancing products and therapies. Product development is focused around Homspera(TM), our proprietary compound that is derived from homeostatic substance P, a naturally occurring peptide within the body. The Company's initial area of focus is on the development of products that we believe will treat the suppression of the body's immune system caused by exposure to various forms of radiation, toxic inhalants and viral infectious diseases.

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.

GENERAL

OVERVIEW

IR BioSciences Holdings, Inc. is a development-stage biopharmaceutical company. Through our wholly owned subsidiary, ImmuneRegen BioSciences, Inc., we are engaged in the research and development of health enhancing and potential life saving products. Our product development is focused around Homspera(TM), a proprietary compound that is derived from homeostatic substance P, a naturally occurring peptide. We believe Homspera can be used as treatment for various medical conditions as our preclinical animal studies have shown the compound to have very high anti-inflammatory and immunostimulatory properties when introduced into the body. To date, results from several animal studies and initial toxicology data have shown Homspera to be safe.

Our patents and continued substance P research are derived from discoveries made during research studies funded by the Air Force Office of Scientific Research in early 1991 by our Chief Scientific Officer and Director, Dr. Mark Witten. These studies further showed that the administration of Homspera prevented and reversed the damaging effects of jet fuel exposure in the lungs, as well as protecting and regenerating the immune system. These findings led to early research on treatments for exposure to acute radiation, toxic inhalants, viral infection and on the reversal of lung damage.

Our current area of focus is on the development of Radilex(TM) as a universal protectant against various potential forms of injury caused by chemical, biological, radiological and nuclear threats. We are developing Radilex pursuant to a new rule enacted by the U.S. Food and Drug Administration ("FDA") under which approval may be granted solely on the basis of proof of safety in humans and proof of efficacy in relevant animal species. We have chosen this area of focus initially because we believe that it offers us the best potential to reach a large market quicker and more cost effectively as compared to the development of a drug under a traditional medical indication model.

The majority of our efforts are in the research and development of Radilex as a countermeasure to the effects of radiological and nuclear threats. Because of the high anti-inflammatory and immunostimulatory properties of Radilex that we have witnessed, we believe the compound is well-suited for treating the damaging effects of radiation injury when given shortly after exposure to total body irradiation. We have generated a large amount of data in rodent animal models relating to the activity and safety of both Homspera and Radilex. To date we have completed seven mouse studies in which Radilex was administered after exposure to lethal doses of radiation. In these studies we

witnessed survival rates of up to 100% of the exposed mice.

Based on data collected in our preclinical animal studies, we believe that similar results would be possible in humans. We are now finalizing the protocols that we believe will allow us to initiate pivotal large animal trials that will be necessary for establishing efficacy in treating the effects of exposure to radiation. Within the next twelve months, we expect to begin studies in non-human primates in order to

collect data on the efficacy of Radilex in the treatment of exposure to radiation. In conjunction, we are establishing all of the manufacturing, toxicology and human safety data that will be needed to support a New Drug Application (NDA).

We are continuing to research the efficacy of Radilex as a universal protectant, used to treat not only radiological and nuclear threats, but also as a treatment for exposure to potential chemical and biological threats. We have generated data in preclinical studies indicating that Radilex could conceivably be used in treating respiratory failure caused by exposure to various chemical and biological threats, such as anthrax, ricin poisoning and other poisonous inhalants, as well as infectious diseases such as avian flu and SARS. We are continuing to design and perform studies for the further development of Radilex in treating these potential threats.

We have observed in early preclinical studies that Homspera may have an effect in promoting or accelerating wound healing. We plan to conduct preclinical studies to determine if Homspera could become a candidate for further development as a compound to be used in wound healing. We believe that such an application would have a large potential market and would share synergies with potential uses for Radilex.

Our initial data shows that both Homspera and Radilex can be produced quickly and cost-effectively in large quantities, are easily administered using an inhaler or puffer device, are easy to store and have a reasonable shelf lives. Further, in that Radilex may have efficacy in the treatment of the life-threatening effects of radiation exposure, we believe there may be strong interest by government agencies to stockpile Radilex if it is successfully developed. We believe this would not only provide us with an existing market opportunity, but would also require less infrastructure to market our product, thereby allowing us to commercialize Radilex at a substantially lower cost. We are currently in discussions with drug manufacturers and government officials, both foreign and domestic, with regard to such possibilities.

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

RECENT EVENTS

In October 2004, we completed a private placement, whereby we sold an aggregate of $2,450,000 worth of units to accredited investors (the "Private Placement"). Each unit was sold for $10,000 (the "Unit Price") and consisted of (a) a number of shares of our common stock determined by dividing the Unit Price by $0.125, and (b) a warrant to purchase, at any time prior to the fifth anniversary following the date of issuance of the warrant, a number of shares of our common stock equal to fifty percent (50%) of the number of shares included

within the unit, at a price equal to $0.50 per share of common stock. We issued in the Private Placement an aggregate of 27,560,897 shares of our common stock and warrants to purchase 13,780,449 shares of our common stock. In consideration of the investment, we granted to each investor certain registration rights and anti-dilution rights.

Further to the Private Placement, we entered into a settlement agreement with certain creditors whereby for full and complete satisfaction of claims totaling an aggregate of $157,219 (the "Claim Amount"), we issued to the creditors the following: (a) a number of shares of our common stock determined by dividing the Claim Amount by $0.125, and (b) warrants to purchase, at any time prior to the fifth anniversary following the date of issuance of the warrant, a number of shares of our common stock equal to fifty percent (50%) of the number of shares described above, at a price equal to $0.50 per share of common stock. The warrants are identical to the warrants issued in the Private Placement. Pursuant to the settlement we issued an aggregate of 1,257,746 shares of common stock and warrants to purchase 628,873 shares of common stock. Under the terms of the settlement agreement, the creditors released us from all claims, known or unknown, relating to the Claim Amount.

Pursuant to the terms of a placement agency agreement, dated September 3, 2004, by and between us and Joseph Stevens & Co., Inc., we issued 4,900,000 shares of our common stock to Joseph Stevens & Co., Inc. or its designees, upon the closing of the Private Placement. The shares were issued as consideration for the services of Joseph Stevens & Co., Inc. as our placement agent in the Private Placement.

We also previously issued convertible promissory notes in the aggregate principal amount of $558,500. Immediately upon the closing of the Private Placement, and in accordance with the terms of the promissory notes, all outstanding principal and accrued interest converted into 6,703,151 shares of our common stock.

Effective December 17, 2004, Eric Hopkins resigned from his position as our Chief Financial Officer.

Effective December 22, 2004, Steven J. Scronic resigned from his position as our Corporate Secretary.

Our board of directors appointed John N. Fermanis to serve as our Chief Financial Officer, effective as of December 22, 2004. Our Board resolved to issue 100,000 shares of registered common stock to Mr. Fermanis for his acceptance of this position.

Our board of directors appointed Michelle R. Laroche to serve as our Corporate Secretary, effective as of December 22, 2004.

We also previously issued convertible promissory notes in the aggregate principal amount of $35,000. On December 24, 2004 all outstanding principal and accrued interest was forgiven by the noteholder. Consideration of $100.00 was paid by us to the noteholder. Under the terms of the agreement, the noteholder released us from all claims, known or unknown, relating to the amount owed.

In January 2005, we made a tender offer to temporarily reduce the exercise price of certain warrants issued in October 2004 from $0.50 to $0.20 per share. The tender offer expired on March 4, 2005. We accepted for exercise a total of 6,600,778 warrants validly tendered and not withdrawn pursuant to the terms of the tender offer, which represents approximately 48% of the aggregate

13,780,449 warrants that were subject to the offer.

HOMSPERA AND SUBSTANCE P

Homspera is a proprietary compound created by chemically modifying substance P to increase desirable properties. The chemical name for Homspera is Sar9, Met(O2)11-substance P.

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.

Our patents and continued research and development efforts are derived from discoveries made during the early 1990s by our Chief Scientific Officer and Director, Dr. Mark Witten as a spin-off of an Air Force grant. During this research it was 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 Sar9, Met(O2)11-substance P prevented and reversed the effects of jet fuel exposure in the lungs, as well as protecting and regenerating the immune system. These findings led to early research on treatments for exposure to acute radiation, toxic inhalants and viral infection and on the reversal of lung damage.

We believe that Homspera and its derivatives are able to be used as treatments for a diverse array of ailments and bodily injury as it regulates cellular death and survival. Further, Homspera is highly selective in nature and as a substance P receptor agonist it blocks the receptor so that other mediators cannot attach to it and may prevent inflammation and cell death.

PRODUCTS IN DEVELOPMENT

RADILEX(TM)

We are currently focusing our development efforts on Radilex as a potential countermeasure for exposure to lethal doses of radiation in humans. As traditional efficacy studies would require healthy human volunteers to be exposed to potentially lethal effects of radiation, Radilex is being developed

pursuant to a new rule enacted by the U.S. Food and Drug Administration (FDA) under which approval may be granted solely on the basis of proof of efficacy in relevant animal species and proof of safety in humans. We believe that this will not only greatly accelerate the development of Radilex(TM) but also will substantially reduce our development costs and allow us to enter the marketplace more quickly as compared to following a traditional drug development program.

To date we have completed seven radiation studies using Radilex on mice to determine dose response to radiation, the maximum efficacious dose, the impact on survival and to distinguish survival response between aerosol versus intra muscular delivery. In each of these studies mice were exposed to varying levels of radiation. In the fifth study we determined that Radilex aerosol treatment at a dose of 50 iM can induce a survival rate of 50% in mice at 90 days post-radiation exposure to an administered lethal (7.75 Gy) dose of radiation. Further, it was observed that these mice had normal immune system function at the 90-day post-radiation time point compared to longitudinal control mice. In June 2004 we performed our sixth study, conducted at the request of the Division of Counter-Terrorism of the U.S. Food and Drug Administration to determine the optimum delivery method. In this study a 2iM dose of Radilex in a 0.05mL solution was delivered daily via muscle injection. In the study we observed that delivery by aerosol was superior methodology over direct muscle injection for the administration of Radilex. In our seventh mouse study, we increased the dosage to 75iM and held the mice in a Biolevel II facility with a low bacterial load. At 17 days post-exposure we observed a one hundred percent survival rate in the mice given Radilex.

Currently, we are finalizing the protocols for an eighth mouse study. We are designing this study to achieve proof of concept, as well as obtaining the optimum dosing regime, drug dosage levels and delivery method. This study will evaluate the survival impact of Radilex following exposure to various gamma radiation levels; to validate the effects of Radilex on PARP-1 levels/expression following irradiation; to determine Radilex levels in major organs; to determine the impact of Radilex on survival when administered 12, 24 and 36 hours following colbalt radiation exposure; and, to validate and compare survival rates of aerosol versus intra muscular delivery. We expect this study to begin within the next 60 days.

We are also finalizing the protocols that we believe will allow us to initiate pivotal large animal trials that will be necessary for establishing efficacy. We expect these studies to begin within the next 12 to 18 months. In conjunction with this, we are establishing protocols for toxicology and human safety studies that will be needed to support a New Drug Application (NDA).

We are also researching the efficacy of Radilex as a treatment for exposure to various chemical and biological agents. We have generated data in preclinical studies indicating that Radilex could potentially be used in treating respiratory failure caused by exposure to various chemical and biological threats, such as anthrax, ricin poisoning and other poisonous inhalants, as well as infectious diseases.

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. Severe body injury can result from such exposure including: skin damage; lung radiation injury, similar to Acute Respiratory Distress Syndrome; hematopoietic syndrome, which includes

thrombocytopenia and neutropenia; and, damage to the body's organs. The chance of survival for 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 person'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.

Market for Our Products

Because of past terrorist events, people have expressed much greater 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. In light of the current risk of terrorism, high-risk areas include military installations, major metropolitan areas and those areas surrounding nuclear power plants or spent fuel facilities. Additionally, Radilex could potentially be made available for distribution in the event of a natural disaster or accident to those individuals living near nuclear power plants, spent fuel facilities and those living along transport routes of radioactive materials. The uncertainties of terrorism, natural disasters and accidents coupled with a virtually unlimited number of individuals that could potentially be affected, presents us with significant, untapped market opportunities not only domestically, but also throughout the world.

Based on our studies we believe that Radilex must be administered as soon as possible after exposure to radiation. Due to the suddenness of a potential attack or disaster and the number of people that would be affected, we believe that Radilex would need to be stockpiled to be appropriately distributed. Administration of Radilex can be done quickly and cost effectively using an inhaler or puffer device. In that Radilex may prove effective in the treatment of the life-threatening effects of radiation exposure, we believe there may be strong interest by government agencies to stockpile Radilex if it is successfully developed. We are currently in discussions with drug manufacturers and government officials with regard to such possibilities.

RESEARCH AND DEVELOPMENT

We have spent approximately $150,091 and $42,972 in 2004 and 2003, respectively, in research and development activities. From our inception in October 2002, we have spent $193,063 in research and development activities.

COMPETITION

We are engaged in segments of the biopharmaceutical industry that are intensely competitive and rapidly changing. Based on recent world events and aggressive governmental legislation, we believe a large market opportunity has developed. Given this large potential market, numerous pharmaceutical and

biotechnology companies have directed their research efforts toward developing therapeutics to treat the same indications that we are researching.

If successfully developed and approved, we believe that there is a significant market for Radilex relating to the treatment of exposure to radiation and poisonous inhalants. We anticipate that, even if we successfully

develop Homspera and Radilex and they are approved for marketing, we will face intense and increasing competition in the future as new products enter the market and advanced technologies become available. There can be no assurance that existing products or new products for the treatment of such ailments developed by competitors, including Hollis-Eden Pharmaceuticals, Inc., VaxGen, Inc., Acambis plc, Emergent BioSolutions, Inc. and other larger biopharmaceutical companies, will not be more effective or more effectively marketed and sold. Competitive products or the development by others of a cure or new treatment methods may render our technologies and products and compounds obsolete, noncompetitive or uneconomical prior to our recovery of development or commercialization expenses incurred with respect to any such technologies or products or compounds.

We believe that due to the global political environment that time to market is critical in the discovery of an effective countermeasure to radiation exposure and other biological and chemical threats. New developments in areas in which we are conducting our research and development are expected to continue at a rapid pace in both industry and academia. Many of our competitors have significantly greater financial, technical and human resources than us and may be better equipped to develop, manufacture, sell, market and distribute products. In addition, many of these companies have extensive experience in preclinical testing and clinical trials, obtaining FDA and other regulatory approvals and manufacturing and marketing pharmaceutical products. Many of these competitors also have products for use individually or in combination therapy that have been approved or are in late-stage development and operate large, well-funded research and development programs. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and biotechnology companies.

If our product candidates and compounds are successfully developed and approved, we will face competition based on the safety and effectiveness of our products and compounds, the timing and scope of regulatory approvals, availability of manufacturing, sales, marketing and distribution capabilities, reimbursement coverage, price and patent position. There can be no assurance that our competitors will not develop more effective or more affordable technology or products, or achieve earlier patent protection, product development or product commercialization than us. Accordingly, our competitors may succeed in commercializing products more rapidly or effectively than us, which could have a material adverse effect on our business, financial condition and results of operations.

GOVERNMENTAL REGULATION

Our technologies are subject to extensive government regulation, principally by the U.S. Food and Drug Administration and state and local authorities in the United States and by comparable agencies in foreign countries. Governmental authorities in the United States extensively regulate the pre-clinical and clinical testing, safety, efficacy, research, development, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution, among other things, of pharmaceutical products under various federal laws including the Federal Food, Drug and Cosmetic Act, or FFDCA, and under comparable laws by the states and in most foreign countries.

Domestic Regulation

In the United States, the FDA, under the FFDCA, the Public Health Service Act and other federal statutes and regulations, subject pharmaceutical and biologic products to rigorous review. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or allow us to manufacture or market our products or

product candidates, and we may be criminally prosecuted. The FDA also has the authority to discontinue or suspend manufacture or distribution, require a product withdrawal or recall or revoke previously granted marketing authorizations, if we fail to comply with regulatory standards or if we encounter problems following initial marketing.

PROJECT BIOSHIELD

The U.S. government, in response to the increased threat to its citizens, has enacted Project BioShield, a comprehensive effort to develop and make available modern, effective drugs and vaccines to protect against attack by biological and chemical weapons or other dangerous pathogens. Project BioShield will:

- Ensure that resources are available to pay for "next-generation" medical countermeasures. Project BioShield will allow the government to buy improved vaccines or drugs for smallpox, anthrax, and botulinum toxin. Use of this authority is currently estimated to be $6 billion over ten years. Funds would also be available to buy countermeasures to protect against other dangerous pathogens, such as Ebola and plague, as soon as scientists verify the safety and effectiveness of these products.

- Strengthen the development capabilities of the National Institute of Health ("NIH") by speeding research and development on medical countermeasures based on the most promising recent scientific discoveries.

- Give FDA the ability to make promising treatments quickly available in emergency situations. This tightly controlled new authority can make the newest treatments widely available to patients who need it in a crisis.

Project BioShield has three major components:

1. Spending Authority for the Delivery of Next-Generation Medical Countermeasures. This authority will enable the government to purchase vaccines and other therapies as soon as experts believe that they can be made safe and effective, ensuring that the private sector devotes efforts to developing the countermeasures.

2. New NIH Programs to Speed Research and Development on Medical Countermeasures. NIH's usual methods for supporting research and development on conventional diseases have been extremely effective in those areas but may not always be suited to meet the urgent demands posed by the risk of terrorism. The new authorities would apply only to support research and development on bioterrorism threat agents.

3. New FDA Emergency Use Authorization for Promising Medical Countermeasures Under Development. Some of the most promising treatments for a terrorist agent may still be under formal FDA review when an attack occurs. This will improve access to a potentially beneficial treatment in an emergency situation, when it is most likely to save lives, even if it has not yet been proven to be suitable for routine general use or has not completed the formal process for full FDA licensure.

Project BioShield contains provisions enabling the U.S. Department of Health and Human Services ("HHS") to begin purchasing new medical countermeasures for the Strategic National Stockpile in advance of formal FDA approval. This provision, known as an Emergency Use Authorization, has already been implemented for other development stage medical countermeasures to weapons of mass destruction.

As the result of the Project BioShield legislation, the Administration has already begun the process of acquiring several new medical countermeasures. In late 2004, the HHS issued a Request for Information ("RFI") for therapeutics to treat ARS. In December 2004 we filed a formal response to this request detailing the potential for Radilex in this indication.

If we are unable to develop Radilex under the legislation enacted by Project BioShield, we will be required to follow the traditional FDA approval process and guidelines. We believe that approval for Radilex under the traditional process would be considerably more costly and time consuming.

FDA Approval Process

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

The FDA does not apply a single regulatory scheme to human tissues and the products derived from human tissue. On a case-by-case basis, the FDA may choose to regulate such products as transplanted human tissue, medical devices or biologics. A fundamental difference in the treatment of products under these classifications is that the FDA generally permits human tissue for transplantation to be commercially distributed without marketing approval. In contrast, products regulated as medical devices or biologics usually require such approval.

The process required by the FDA before a new drug or biologic may be marketed in the United States generally involves the following:

- completion of pre-clinical laboratory tests or trials and formulation studies;
- submission to the FDA of an IND for a new drug or biologic, which must become effective before human clinical trials may begin;

- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug or biologic for its intended use; and,

- submission and approval of a New Drug Application, or NDA, for a drug, or a BLA for a biologic.

Pre-clinical tests include laboratory evaluation of product chemistry formulation and stability, as well as studies to evaluate toxicity. In view of the nature of our product candidates and our prior clinical experience with our product candidates, we concluded that it was reasonably safe to initiate clinical trials and that the clinical trials would be adequate to further assess both the safety and efficacy of our product candidates. The results of pre-clinical testing, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application. The FDA requires a 30-day waiting period after the filing of each IND application before clinical trials may begin, in order to ensure that human research subjects will not be exposed to unreasonable health risks. At any time during this 30-day period or at any time thereafter, the FDA may halt proposed or ongoing clinical trials, or may authorize trials only on specified terms. The IND application process may become extremely costly and substantially delay development of our products. Moreover, positive results of pre-clinical tests will not necessarily indicate positive results in clinical trials.

The sponsor typically conducts human clinical trials in three sequential phases, which may overlap. These phases generally include the following:

Phase I: The product is usually first introduced into healthy humans or, on occasion, into patients, and is tested for safety, dosage tolerance, absorption, distribution, excretion and metabolism.

Phase II: The product is introduced into a limited patient population to:

- assess its efficacy in specific, targeted indications;

- assess dosage tolerance and optimal dosage; and,

- identify possible adverse effects and safety risks.

Phase III: These are commonly referred to as pivotal studies. If a product is found to have an acceptable safety profile and to be potentially effective in Phase II clinical trials, new clinical trials will be initiated to further demonstrate clinical efficacy, optimal dosage and safety within an expanded and diverse patient population at geographically-dispersed clinical study sites.

If the FDA does ultimately approve the product, it may require post-marketing testing, including potentially expensive Phase IV studies, to monitor its safety and effectiveness.

Clinical trials must meet requirements for Institutional Review Board, or IRB, oversight, informed consent and the FDA's Good Laboratory Practices. Prior to commencement of each clinical trial, the sponsor must submit to the FDA a clinical plan, or protocol, accompanied by the approval of the committee

responsible for overseeing clinical trials at one of the clinical trial sites. The FDA and the IRB at each institution at which a clinical trial is being performed may order the temporary or permanent discontinuation of a clinical trial at any time if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients.

The sponsor must submit to the FDA the results of the pre-clinical and clinical trials, together with, among other things, detailed information on the manufacturing and composition of the product, in the form of an NDA, or, in the case of a biologic, a BLA. Once the submission has been accepted for filing, the FDA has 180 days to review the application and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, but the FDA is not bound by the recommendation of an advisory committee.

It is possible that our product candidates will not successfully proceed through this approval process or that the FDA will not approve them in any specific period of time, or at all. The FDA may deny or delay approval of applications that do not meet applicable regulatory criteria, or if the FDA determines that the clinical data do not adequately establish the safety and efficacy of the product. Satisfaction of FDA pre-market approval requirements for a new biologic is a process that may take several years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. The FDA reviews these applications and, when and if it decides that adequate data are available to show that the product is both safe and effective and that other applicable requirements have been met, approves the drug or biologic for marketing. Government regulation may delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon our activities. Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Upon approval, a product candidate may be marketed only for those indications approved in the BLA or NDA and may be subject to labeling and promotional requirements or limitations, including warnings, precautions, contraindications and use limitations, which could materially impact profitability. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-market regulatory standards is not maintained or if safety, efficacy or other problems occur after the product reaches the marketplace.

The FDA may, during its review of an NDA or BLA, ask for additional test data. If the FDA does ultimately approve the product, it may require post-marketing testing, including potentially expensive Phase IV studies, to monitor the safety and effectiveness of the product. In addition, the FDA may, in some circumstances, impose restrictions on the use of the product, which may be difficult and expensive to administer and may require prior approval of promotional materials.

Ongoing FDA Requirements

Before approving an NDA or BLA, the FDA will inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facilities are in compliance with the FDA's current Good Manufacturing Practices, or cGMP, requirements which govern the manufacture,

holding and distribution of a product. Manufacturers of biologics also must comply with the FDA's general biological product standards. Following approval, the FDA periodically inspects drug and biologic manufacturing facilities to ensure continued compliance with the cGMP requirements. Manufacturers must continue to expend time, money and effort in the areas of production, quality control, record keeping and reporting to ensure full compliance with those requirements. Failure to comply with these requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing, seizure of product, voluntary recall of product, withdrawal of marketing approval or civil or criminal penalties. Adverse experiences with the product must be reported to the FDA and could result in the imposition of marketing restrictions through labeling changes or market removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

The labeling, advertising, promotion, marketing and distribution of a drug or biologic product also must be in compliance with FDA and FTC requirements which include, among others, standards and regulations for direct-to-consumer advertising, industry-sponsored scientific and educational activities, and promotional activities involving the internet. The FDA and FTC have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a Warning Letter directing the company to correct deviations from regulatory standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA and enforcement actions that can include seizures, injunctions and criminal prosecution.

Manufacturers are also subject to various laws and regulations governing laboratory practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances in connection with their research. In each of the above areas, the FDA has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products and deny or withdraw approvals.

HIPAA Requirements

Other federal legislation may affect our ability to obtain certain health information in conjunction with our research activities. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, mandates, among other things, the adoption of standards designed to safeguard the privacy and security of individually identifiable health information. In relevant part, the U.S. Department of Health and Human Services, or HHS, has released two rules to date mandating the use of new standards with respect to such health information. The first rule imposes new standards relating to the privacy of individually identifiable health information. These standards restrict the manner and circumstances under which covered entities may use and disclose protected health information so as to protect the privacy of that information. The second rule released by HHS establishes minimum standards for the security of electronic health information. While we do not believe we are directly regulated as a covered entity under HIPAA, the HIPAA standards impose requirements on covered entities conducting research activities regarding the use and disclosure of individually identifiable health information collected in the course of conducting the research. As a result, unless they meet these HIPAA requirements, covered entities conducting clinical trials for us may not be able to share with us any results from clinical trials that include such health information.

In addition to the statutes and regulations described above, we are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future federal, state and local regulations.

MANUFACTURING

We do not have, and do not intend to establish, manufacturing facilities to produce Radilex or any future products. We have used and expect to continue to use third party manufacturers to obtain synthetic peptides. We believe 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 used in scientific and genomic research, biotechnology, pharmaceutical development and the diagnosis of disease and chemical manufacturing. We believe that the synthetic substance P and other materials necessary to produce Homspera and Radilex are readily available from various sources, and several suppliers are capable of supplying such in both clinical and commercial quantities. We have established relationships to fulfill our near-term production needs and we have had extensive discussions to fulfill any future commercial production needs.

The manufacture of our product candidates or any future products, whether done by outside contractors as planned or internally, will be subject to rigorous regulations, including the need to comply with the FDA's current Good Manufacturing Practice (GMP) standards. As part of obtaining FDA approval for each product, each of the manufacturing facilities must be inspected, approved by and registered with the FDA. In addition to obtaining FDA approval of the prospective manufacturer's quality control and manufacturing procedures, domestic and foreign manufacturing facilities are subject to periodic inspection by the FDA and/or foreign regulatory authorities.

DISTRIBUTION

If Radilex receives approval from the FDA, we will attempt to commercialize the product. Upon such approval, we intend to use our best efforts to market Radilex as a treatment to the damaging effects of radiation injury that result after exposure to total body irradiation, and possibly as a universal protectant against exposure to various biological and chemical threats. We intend to offer for sale the product to various governmental agencies at the local, state and federal levels, both domestically and outside the United States.

Prior to FDA approval, Radilex may become eligible for purchase by the U.S. government. Project BioShield legislation contains provisions enabling the HHS to begin purchasing new medical countermeasures for the Strategic National Stockpile in advance of formal FDA approval. This provision, known as an Emergency Use Authorization, has already been implemented for other development stage medical countermeasures to weapons of mass destruction. In that Radilex may have efficacy in the treatment of the life-threatening effects of radiation exposure, we believe there may be strong interest by government agencies to stockpile Radilex if it is successfully developed.

PATENTS

We currently own or have obtained a license to two issued U.S. patents and six pending U.S. patents applications. We also currently own or have obtained two issued foreign patents and two pending foreign patent applications. Our issued patents and patent applications primarily cover the methods whereby Homspera is used in improving pulmonary function and stimulating the immune system. We are in the process of pursuing several other patent applications.

We believe that patents, trademarks, copyrights and other proprietary rights are important to our business. We also rely on trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. We seek to protect our intellectual property rights by a variety of means, including obtaining patents, maintaining trade secrets and proprietary know-how, and technological innovation to operate without infringing on the proprietary rights of others and to

prevent others from infringing on our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, actively seeking patent protection in the United States and foreign countries.

Our success depends in part on our ability to maintain our proprietary position through effective patent claims and their enforcement against our competitors. Although we believe our patents and patent applications provide a competitive advantage, the patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. We do not know whether any of our patent applications will result in the issuance of any patents. Our issued patents, those that may be issued in the future or those acquired by us, may be challenged, invalidated or circumvented, and the rights granted under any issued patent may not provide us with proprietary protection or competitive advantages against competitors with similar technology. In particular, we do not know if competitors will be able to design variations on our treatment methods to circumvent our current and anticipated patent claims. Furthermore, competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for the development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized or marketed, any related patent claim may expire or remain in force for only a short period following commercialization, thereby reducing the advantage of the patent.

We also rely upon trade secrets, confidentiality agreements, proprietary know-how and continuing technological innovation to remain competitive, especially where we do not believe patent protection is appropriate or obtainable. We continue to seek ways to protect our proprietary technology and trade secrets, including entering into confidentiality or license agreements with our employees and consultants, and controlling access to and distribution of our technologies and other proprietary information. While we use these and other reasonable security measures to protect our trade secrets, our employees or consultants may unintentionally or willfully disclose our proprietary information to competitors.

Our commercial success will depend in part on our ability to operate without infringing upon the patents and proprietary rights of third parties. It is uncertain whether the issuance of any third party patents would require us to alter our products or technology, obtain licenses or cease certain activities. Our failure to obtain a license to technology that we may require to discover, develop or commercialize our future products may have a material adverse impact on us. One or more third-party patents or patent applications may conflict with patent applications to which we have rights. Any such conflict may substantially reduce the coverage of any rights that may issue from the patent applications to which we have rights. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO to determine priority of invention.

We may collaborate in the future with other entities on research,

development and commercialization activities. Disputes may arise about inventorship and corresponding rights in know-how and inventions resulting from the joint creation or use of intellectual property by us and our collaborators, partners, licensors and consultants. As a result, we may not be able to maintain our proprietary position.

EMPLOYEES

As of December 31, 2004, we had five total employees, four contract employees and one full-time employee. Our sole full time employee is our Chief Executive Officer, Michael K. Wilhelm,. None of our 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 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 the twelve months ended December 31, 2004 was $5,305,407. As of December 31, 2004, we had an accumulated deficit of $7,208,027.

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 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 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:

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

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

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.

As of December 31, 2004, our cash and cash equivalents totaled approximately $970,114 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 12 months. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. We may 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:

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

If we cannot raise additional funds when needed, or on acceptable terms, we will not be able to continue to develop our drug candidates.

We require substantial working capital to fund our operations. Since we do not expect to generate 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, 2004 was $(593,533) 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 Homspera. In addition, we expect to utilize Homspera 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 Homspera, we may have to modify or cease production of the products. As all of our applications utilize or will utilize Homspera, any findings that Homspera is unsafe or ineffective would severely harm our business operations, since all of our primary revenue sources would be negatively affected by such findings.

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

Our failure to develop and commercialize products successfully will cause us to cease operations. Our potential therapies utilizing Homspera 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 Homspera. We currently are focusing our core competencies on Homspera although there may be no assurance that we will be successful in so doing.

Our therapies and technologies utilizing Homspera is at early stages of development and may not be shown to be safe or effective and may never receive regulatory approval. Our technologies utilizing Homspera 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 permitted, any potential products based on Homspera may not be successfully developed or shown to be safe or effective.

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 Unites 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 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.

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 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:

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

- unforeseen safety issues.

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

- labeling and advertising requirements, restrictions or limitations, including the inclusion of warnings, precautions, contra-indications or use limitations that could have a material impact on the future profitability of our applications;

- testing and surveillance to monitor our future products and their continued compliance with regulatory requirements;

- submitting products for inspection and, if any inspection reveals that the product is not in compliance, prohibiting the sale of all products;

- suspending manufacturing; or,

- withdrawing marketing clearance.

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:

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

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

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

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 Homspera 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 Homspera are readily available from various sources, and several suppliers are capable of supplying substance P in both clinical and commercial quantities, our dependence 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 Homspera or any other proposed products will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health coverage insurers, managed care organizations and other organizations. Failure to obtain appropriate reimbursement may prevent us from successfully commercializing Homspera or any proposed products. Third-party payers are increasingly challenging the prices of medical products and services. If purchasers or users of Homspera or any such other proposed products are not able to obtain adequate reimbursement for the cost of using such products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved health care products and whether adequate third party coverage will be available.

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

Our ability to market and commercialize Homspera depends on the acceptance and utilization of Homspera by the medical community. We will need to develop commercialization initiatives designed to increase awareness about us

and Homspera among targeted audiences, including public health activists and community-based outreach groups in addition to the investment community. Currently, we have not

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

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 MARKET SHARE 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 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.

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 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.

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 propriety 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 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.

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 form 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:

- biological or medical discoveries by competitors;
- public concern about the safety of our drug candidates;
- delays in the conduct or analysis of our preclinical or clinical studies;
- unfavorable results from preclinical or clinical studies;
- unfavorable developments concerning patents or other proprietary rights; or
- 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 $0.09 to $1.00 between January 1, 2004 and April 3, 2005.

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

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.

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

Certain of our stockholders have the right to register securities for resale that they hold pursuant to registration rights agreements. We 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. On November 24, 2004, we filed a registration statement on Form SB-2 to register shares of our common stock that may be sold from time to time by the selling stockholders named therein.

The registration and subsequent sales of shares of our common stock will likely

have an adverse effect on the market price of our common stock.

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

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

ITEM 2. DESCRIPTION OF PROPERTIES

Our corporate headquarters are currently located at 4021 N. 75th Street, Suite 201, Scottsdale, Arizona 85251, where we have leased approximately 1,800 square feet of office space through September 30, 2005. Our rent expense is $2,614 per month. We believe that our facilities are adequate for our current needs and suitable additional or substitute space will be available in the future to replace our existing facilities, if necessary, or accommodate expansion of our operations.

ITEM 3. LEGAL PROCEEDINGS

On December 13, 2001, service of process was effectuated upon GPN Network, Inc. with regard to a fee agreement between GPN Network, Inc. and Silver & Deboskey, a Professional Corporation located in Denver, Colorado. The complaint sought compensation for legal services allegedly rendered to DermaRx Corp. On November 7, 2002, the District Court in Denver, Colorado rendered judgment in favor of Silver & Deboskey in the amount of $28,091. At December 31, 2004, we had not paid any of this amount.

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

No matters were submitted to a vote of security holders during the fourth quarter of 2004.

PART II

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

Our common stock is approved for quotation on the NASD OTC Bulletin Board under the symbol "IRBO".

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.

COMMON STOCK		HIGH	LOW
2003			
	1st Quarter	$ 0.01	$ 0.01
	2nd Quarter	$ 0.20	$ 0.01
	3rd Quarter	$ 4.50	$ 0.55
	4th Quarter	$1.125	$0.275
2004			
	1st Quarter	$ 1.00	$ 0.32
	2nd Quarter	$ 0.51	$ 0.11
	3rd Quarter	$ 0.19	$ 0.09
	4th Quarter	$ 0.40	$ 0.15

On April 3, 2005, the closing price of our common stock as reported by the OTC Bulletin Board was $0.45 per share. There were approximately 520 shareholders of record and beneficial stockholders of our common stock as of such date. We have not paid any dividends on our common stock since inception and do not intend to do so in the foreseeable future.

UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

In October 2004 we entered into a settlement agreement with a certain creditor whereby for full and complete satisfaction of claims totaling $5,071.00, we issued to the creditor the following: (a) 67,614 shares of our common stock, determined by dividing the amount owed by $0.075, and (b) warrants to purchase, at any time prior to the fifth anniversary following the date of issuance of the warrant, a number of shares of our common stock equal to two thousand five hundred (2,500), at a price equal to $0.50 per share of common stock. Under the terms of the settlement agreement, the creditor released us from all claims, known or unknown, relating to the amount owed. The securities were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder. The creditor qualified as an accredited investor (as defined by Rule 501 under the Securities Act of 1933, as amended).

On November 18, 2004 we issued warrants to a member of our Bioterrorism Preparedness Advisory Board to purchase, at any time prior to the third anniversary following the date of issuance of the warrant, a number of shares of our common stock equal to 50,000, at a price equal to $0.125 per share of common stock for advice on logistics, introductions to various organizations and attendance of meetings. The securities were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder. The investor qualified as an accredited investor (AS defined by Rule 501 under the Securities Act of 1933, as amended).

On December 16, 2004 we issued warrants to a member of our Oncology and Dermatology Advisory Board to purchase, at any time prior to the third anniversary following the date of issuance of the warrant, a number of shares of our common stock equal to 10,000, at a price equal to $0.50 per share of common stock for advice on potential oncology applications for Homspera. The securities

were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder. The investor qualified as an accredited investor (as defined by Rule 501 under the Securities Act of 1933, as amended)..

In January 2005, we made a tender offer to temporarily reduce the exercise price of certain warrants issued in October 2004 from $0.50 to $0.20 per share. The tender offer expired on March 4, 2005. We accepted for exercise a total of 6,600,778 warrants validly tendered and not withdrawn pursuant to the terms of the tender offer, which represents approximately 48% of the aggregate 13,780,449 warrants that were subject to the offer. The tender offer was made in reliance upon exemption from registration pursuant to Sections 3(a)(9), which provide an exemption for any security exchanged by the issuer with its existing

security holders where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange. We did not pay or give any commission or other remuneration to any person for soliciting the tender offer. The tender offer also falls within Section 4(2) of the Securities Act since all the investors were current holders of the warrants and received their securities from the October 2004 private placement or from issuances in October 2004 pursuant to the terms of settlement agreements or convertible promissory notes. These transactions were conducted under Section 4(2) and the rules and regulations promulgated thereunder, including Regulation D.

DIVIDENDS AND DISTRIBUTIONS

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

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

THE FOLLOWING DISCUSSION CONTAINS FORWARD-LOOKING STATEMENTS THAT INVOLVE RISKS AND UNCERTAINTIES. SEE "FORWARD-LOOKING STATEMENTS" ABOVE. THIS DISCUSSION AND ANALYSIS SHOULD BE READ IN CONJUNCTION WITH THE FINANCIAL STATEMENTS AND NOTES INCLUDED ELSEWHERE IN THIS REPORT.

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

EXCEPT FOR HISTORICAL INFORMATION CONTAINED HEREIN, THE MATTERS DISCUSSED IN THIS ANNUAL REPORT ARE FORWARD-LOOKING STATEMENTS THAT ARE SUBJECT TO CERTAIN RISKS AND UNCERTAINTIES THAT COULD CAUSE ACTUAL RESULTS TO DIFFER MATERIALLY FROM THOSE SET FORTH IN SUCH FORWARD-LOOKING STATEMENTS. SUCH FORWARD-LOOKING STATEMENTS MAY BE IDENTIFIED BY THE USE OF CERTAIN FORWARD-LOOKING TERMINOLOGY, SUCH AS "MAY," "EXPECT," "ANTICIPATE," "INTEND," "ESTIMATE," "BELIEVE," OR COMPARABLE TERMINOLOGY THAT INVOLVES RISKS OR UNCERTAINTIES. ACTUAL FUTURE

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

OVERVIEW

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

the operations of GPN Network, Inc. in their entirety and began looking for appropriate merger partners. Our objective became the acquisition of an operating company with the potential for growth in exchange for our securities. In July 2003, we effected a reverse merger with ImmuneRegen BioSciences, Inc. and adopted our current business model. In July 2003, we effected a 1-for-20 reverse stock split, and in April 2004, we effected a 2-for-1 stock split. ImmuneRegen BioSciences, Inc. was incorporated in October 2002; all information contained herein refers to the operations of ImmuneRegen BioSciences, Inc., our wholly-owned operational subsidiary.

GENERAL

IR BioSciences Holdings, Inc. is a development-stage biopharmaceutical company. Through our wholly owned subsidiary, ImmuneRegen BioSciences, Inc., we are engaged in the research and development of health enhancing and potential life saving products. Our product development is focused around Homspera, a proprietary compound that is derived from homeostatic substance P, a naturally occurring peptide. We believe Homspera can be used as treatment for various medical conditions as our preclinical animal studies have shown the compound to have very high anti-inflammatory and immunostimulatory properties when introduced into the body. To date, results from several animal studies and initial toxicology data have shown Homspera to be safe. Currently, we own or have obtained a license to 4 issued U.S. and foreign patents and 8 pending U.S. and foreign patent applications. As we continue our research and development efforts we will look to add to our portfolio of patents and trademarks.

PLAN OF OPERATIONS

We expect to continue to incur increasing operating losses for the foreseeable future, primarily due to our continued research and development

activities attributable to new and existing products and general and administrative activities.

Due to our liquidity and limited cash available our spending on research and development activities in 2003 and most of 2004 was limited. We spent approximately $150,091 and $42,972 in 2004 and 2003, respectively, in research and development activities related to the development of Radilex as a universal protectant against the effects of chemical, biological, radiological and nuclear threats. From our inception in October 2002, we have spent $193,063 in research and development activities. These costs include the manufacture and delivery of our drug by third party manufacturers, payments to Contract Research Organizations ("CRO") for consulting related to our studies and costs of performing such studies.

We anticipate that during the next 12 months we will increase our research and development activities by approximately $450,000 to a total of approximately $600,000 in an effort to further develop Radilex as a universal protectant against chemical, biological, radiological and nuclear threats. The drug development, clinical trial and regulatory process is lengthy, expensive and uncertain and subject to numerous risks including, without limitation, the following risks discussed under "Risk Factors" - "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.," "If We Fail To Successfully Develop And Commercialize Products, We Will Have To Cease Operations.;" and, "The Lengthy Product Approval Process And Uncertainty Of Government Regulatory Requirements May Delay Or Prevent Us From Commercializing Proposed Products."

Our major research and development projects include:

Development of Radilex as a countermeasure to the effects of radiological and nuclear threats.

Because of the high anti-inflammatory and immunostimulatory properties of Radilex that we have witnessed, we believe the compound is well-suited for treating the damaging effects of radiation injury when given shortly after exposure to total body irradiation. We have generated a large amount of data in rodent animal models relating to the activity and safety of Radilex.

We are currently preparing the protocols for our eighth mouse study in which we will further validate our prior studies by collecting additional data as requested by the FDA and NIH. We expect to begin the eighth study within the next 60 days. We estimate that the study will be completed within 3 months upon commencement at an estimated cost of $70,000. Upon completion of the aforementioned study we will prepare the protocols necessary for a non-human primate study to test the efficacy of Radilex as a treatment to acute radiation sickness. We expect this study to begin within the next twelve months. We believe that preliminary results will be available within 90 days from beginning of study, with analysis within an additional 60 to 90 days. We have budgeted approximately $310,000 for expenses related to this study in our fiscal year ending December 31, 2005. We expect an additional $450,000 will be required to complete this study in 2006.

If we are successful in completing the study and achieve the desired results, we will submit the necessary documentation to the FDA and other regulatory agencies for approval. We believe that Radilex can be developed and

approval granted under Project BioShield, if so, we believe that the approval process will be significantly shortened and less costly. If approval for Radilex is granted in a timely manner, we expect to begin to commercialize our product immediately thereafter. We are anticipating revenues from the sale of Radilex beginning in calendar year 2006/2007 as a treatment to the effects caused by irradiation.

If product development or approval does not occur as scheduled our time to reach market will be lengthened and our costs will likely increase. Additionally, we may be requested to expand our findings to gather additional data or we may not achieve the desired results. If so, we may have to design new protocols and conduct additional studies. This will increase our costs and delay the time to market for Radilex. Any of these occurrences would have a material negative impact on our business and our liquidity as it may cause us to seek additional capital sooner than expected and allow our competitors to successfully enter the market ahead of us.

Development of Radilex as a countermeasure to the effects of chemical and biological threats.

We are currently continuing to research the efficacy of Radilex as a universal protectant to be used also as a treatment for exposure to various chemical and biological threats. We have generated data in preclinical studies indicating that Radilex could potentially be used in treating respiratory failure caused by exposure to various chemical and biological agents, such as anthrax, ricin poisoning and other poisonous inhalants, as well as, infectious diseases such as avian flu and SARS. We are continuing to design and perform studies for the further development of Radilex for these applications. We have budgeted approximately $35,000 for studies related to the use of Radilex as a treatment for exposure to various chemical and biological threats. We anticipate additional studies to begin in the third or fourth quarters of calendar 2005 and continue on an ongoing basis over the next three years. If we are successful in achieving desirable results, we intend to design the protocols and begin studies for these indications, when capital is available. As we have only collected preliminary data and additional studies are required, we cannot predict when, if ever, a viable treatment can be commercialized. If we do not observe significant results or we lack the capital to further the development, we may abandon such research and development efforts; thereby limiting our future potential revenues.

Development of Homspera in the promotion of wound healing.

We have observed in early preclinical studies that Homspera may have an effect in promoting or accelerating wound healing. Within the next three months we plan to begin preclinical studies to determine if Homspera could become a candidate for further development as a compound used in wound healing. We believe that such an application would have a large potential market and would share synergies with potential uses for Radilex as a universal protectant. We expect to begin studies regarding the use of Homspera in the promotion of wound healing in the third quarter of calendar 2005. We do not have any research and development expenses associated with the use of Homspera in wound healing in 2004 or 2003, as our observations we generated in our radiation studies. We have budgeted approximately $60,000 for the costs of such studies over the next twelve months. We anticipate the completion of such studies within eight months

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

We will need to generate significant revenues from product sales and or related royalties and license agreements to achieve and maintain profitability. Through December 31, 2004, we had no revenues from any product sales, royalties or licensing fees, and have not achieved profitability on a quarterly or annual basis. Our ability to achieve profitability depends upon, among other things, our ability to develop products, obtain regulatory approval for products under development and enter into agreements for product development, manufacturing and commercialization. Moreover, we may never achieve significant revenues or profitable operations from the sale of any of our products or technologies.

OFF-BALANCE SHEET ARRANGEMENTS

There were no off-balance sheet arrangements made in 2004.

REVENUES

We have not generated any revenues from operations from our inception. We believe we will begin earning revenues from operations during calendar year 2007 as we transition from a development stage company to that of an active growth and acquisition stage company.

COSTS and EXPENSES

From our inception through December 31, 2004, we have incurred losses of $7,208,027. These expenses were associated principally with equity-based compensation to employees and consultants, product development costs and professional services.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2004, we had current assets of $976,827 consisting of cash of $970,114 and prepaid services of $6,713. Also, at December 31, 2004, we had current liabilities of $383,294, consisting of notes payable net of discount of $75,993 and accounts payable and accrued liabilities of $307,301. This resulted in working capital of $593,533. During the twelve months ended December 31, 2004, we used cash in operating activities of $1,041,182. From the date of inception (October 30, 2002) to December 31, 2004, we had a net loss of $7,208,027 and used cash of $2,074,345 in operating activities. We met our cash requirements from our inception through December 31, 2004 via the private placement of $2,069,046 of our common stock and $983,500 from the issuance of notes payable, net of repayments. In October 2004, we completed a private placement whereby we sold an aggregate of $2,450,000 worth of units to accredited investors. Each unit was sold for $10,000 and consisted of (a) a number of shares of our common stock determined by dividing the unit price of $10,000 by $0.125, and (b) a warrant to purchase, at any time prior to the fifth anniversary following the date of issuance of the warrant, a number of shares of our common stock equal to fifty percent (50%) of the number of shares included within the unit, at a price equal to $0.50 per share of common stock. We issued an aggregate of 27,560,897 shares of our common stock and warrants to purchase 13,780,449 shares of our common stock in this private placement. In consideration of the investment, we granted to each investor certain registration rights and anti-dilution rights.

In January 2005, we made a tender offer to temporarily reduce the exercise price of certain warrants issued in October 2004 from $0.50 to $0.20 per share. The tender offer expired on March 4, 2005. We accepted for exercise a total of 6,600,778 warrants validly tendered and not withdrawn pursuant to the terms of the tender offer, which represents approximately 48% of the aggregate 13,780,449 warrants that were subject to the offer. We raised an aggregate of $1,211,000 from the tender offer, net of costs.

Since our inception, we have been seeking additional third-party funding. During such time, we have retained a number of different investment banking firms to assist us in locating available funding; however, we have not yet been successful in obtaining any of the long-term funding needed to make us into a commercially viable entity. During the period from October 2004 to March 2005, we were able to obtain financing of $3,590,136 from a series of private placements of our securities (which resulted in net proceeds to us of $3,182,845). All of our current funding is expected to be depleted by the end of January, 2006. Although we are continuing with our efforts to obtain funding to maintain our operations , we cannot assure you that we will be successful or that any funding we receive will be received timely or on commercially reasonable terms. Due to our working capital deficiency, and if we do not receive adequate financing, we will be unable to pay our vendors, lenders and other creditors if we cease our operations, since the net realizable value of our non-current assets will not generate adequate cash. We currently have no commitments for financing. There is no guarantee that we will be successful in raising the funds required.

Until such time, if at all, as we receive adequate funding, we intend to continue to defer payment of all of our obligations which are capable of being deferred, which actions have resulted in some vendors demanding cash payment for their goods and services in advance, and other vendors refusing to continue to do business with us. In the event that we are successful in obtaining third-party funding, we do not expect to generate a positive cash flow from our operations for at least several years, if at all, due to anticipated expenditures for research and development activities, administrative and marketing activities, and working capital requirements and expect to continue to attempt to raise further capital through one or more further private placements.

While we have successfully raised capital to meet our working capital and financing needs in the past through debt and equity financings, additional financing will be required in order to implement our business plan and to meet our current and projected cash flow deficits from operations and development. There can be no assurance that we will be able to consummate future debt or equity financings in a timely manner on a basis favorable to us, or at all. If we are unable to raise needed funds, we will not be able to develop or enhance our 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.

By adjusting our operations and development to the level of capitalization, we believe that we have sufficient capital resources to meet projected cash flow deficits through the next twelve months. However, if thereafter, we are not successful in generating sufficient liquidity from operations or in raising sufficient capital resources, this would have a material adverse effect on our business, results of operations, liquidity and financial condition.

At December 31, 2004, we were in default on one note of $53,900 plus accrued interest of $12,093. Another note for $10,000 was outstanding on

December 31, 2004 but was subsequently repaid. Fifteen notes in the aggregate amount of $558,500 plus accrued interest of $56,757 were converted to equity in October 2004. We are negotiating revised terms which may include converting to equity on the note in default at December 31, 2004 in the aggregate amount of $53,900 plus accrued interest of $12,093.

Pursuant to our employment agreement with Michael Wilhelm, our President and Chief Executive Officer, dated December 16, 2002, we paid a salary of $125,000 and $175,000 to Mr. Wilhelm during the first and second years of his employment, respectively. Thereafter we paid, and will continue to pay, through the term of Mr. Wilhelm's employment, an annual salary of $250,000. Mr. Wilhelm's salary is payable in regular installments in accordance with the customary payroll practices of our company.

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

Under the terms of our consulting agreement with Dr. Mark Witten, one of our founders, we will pay to Dr. Witten a non-refundable fee equal to $5,000 per month.

Acquisition or Disposition of Plant and Equipment

We do not anticipate the sale of any significant property, plant or equipment during the next twelve months. We do not anticipate the acquisition of any significant property, plant or equipment during the next 12 months.

Number of Employees

From our inception through the period ended December 31, 2004, we have relied on the services of outside consultants for services and currently have 3 full time employees. In order for us to attract and retain quality personnel, we anticipate we will have to offer competitive salaries to future employees. We do not anticipate our employment base will significantly change during the next 12 months, other than the addition of one senior level appointment to the position of Senior Vice President of Scientific Development. As we continue to expand, we will incur additional cost for personnel. This projected increase in personnel is dependent upon our generating revenues and obtaining sources of financing. There is no guarantee that we will be successful in raising the funds required or generating revenues sufficient to fund the projected increase in the number of employees.

CRITICAL ACCOUNTING POLICY

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and judgments that affect our reported assets, liabilities, revenues, and expenses, and the disclosure of contingent assets and liabilities. We base our estimates and judgments on historical experience and on various

other assumptions we believe to be reasonable under the circumstances. Future events, however, may differ markedly from our current expectations and assumptions. While there are a number of significant accounting policies affecting our consolidated financial statements; we believe the following critical accounting policy involve the most complex, difficult and subjective estimates and judgments:

- stock-based compensation

Stock-Based Compensation

In December 2002, the FASB issued SFAS No. 148 - Accounting for Stock-Based Compensation - Transition and Disclosure. This statement amends SFAS No. 123 - Accounting for Stock-Based Compensation, providing alternative methods of voluntarily transitioning to the fair market value based method of accounting for stock based employee compensation. FAS 148 also requires disclosure of the method used to account for stock-based employee compensation and the effect of the method in both the annual and interim financial statements. The provisions of this statement related to transition methods are effective for fiscal years ending after December 15, 2002, while provisions related to disclosure requirements are effective in financial reports for interim periods beginning after December 31, 2003.

We elected to continue to account for stock-based compensation plans using the intrinsic value-based method of accounting prescribed by APB No. 25, "Accounting for Stock Issued to Employees," and related interpretations. Under the provisions of APB No. 25, compensation expense is measured at the grant date for the difference between the fair value of the stock and the exercise price.

From its inception, the Company has incurred significant costs in connection with the issuance of equity- based compensation, which is comprised primarily of our common stock and warrants to acquire our common stock, to non-employees. The Company anticipates continuing to incur such costs in order to conserve its limited financial resources. The determination of the volatility, expected term and other assumptions used to determine the fair value of equity based compensation issued to non-employees under SFAS 123 involves subjective judgment and the consideration of a variety of factors, including our historical stock price, option exercise activity to date and the review of assumptions used by comparable enterprises.

We account for equity based compensation, issued to non-employees in exchange for goods or services , in accordance with the provisions of SFAS No. 123 and EITF No. 96-18, "Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services".

Recent Accounting Pronouncements

In April 2003, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 149, Amendment of Statement No. 133 on Derivative Instruments and Hedging Activities. SFAS 149 amends SFAS No. 133 to provide clarification on the financial accounting and reporting of derivative instruments and hedging activities and requires that contracts with similar characteristics be accounted for on a comparable basis. The provisions of SFAS 149 are effective for contracts entered into or modified after June 30, 2003,

and for hedging relationships designated after June 30, 2003. The adoption of SFAS 149 did not have a material impact on the Company's results of operations or financial position.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. SFAS 150 establishes standards on the classification and measurement of certain financial instruments with characteristics of both liabilities and equity. The provisions of SFAS 150 are effective for financial instruments entered into or modified after May 31, 2003 and to all other instruments that exist as of the beginning of the first interim financial reporting period beginning after June 15, 2003. The adoption of SFAS 150 did not have a material impact on the Company's results of operations or financial position.

In December 2003, the FASB issued a revision of SFAS No. 132, "Employers' Disclosures About Pensions And Other Postretirement Benefits." This pronouncement, SFAS No. 132-R, expands employers' disclosures about pension plans and other post-retirement benefits, but does not change the measurement or recognition of such plans required by SFAS No. 87, No. 88, and No. 106. SFAS No. 132-R retains the existing disclosure requirements of SFAS No. 132, and requires certain additional disclosures about defined benefit post-retirement plans. Except as described in the following sentence, SFAS No. 132-R is effective for foreign plans for fiscal years ending after June 15, 2004; after the effective date, restatement for some of the new disclosures is required for earlier annual periods. Some of the interim-period disclosures mandated by SFAS No. 132-R (such as the components of net periodic benefit cost, and certain key assumptions) are effective for foreign plans for quarters beginning after December 15, 2003; other interim-period disclosures will not be required for the Company until the first quarter of 2005. Since the Company does not have any defined benefit post-retirement plans, the adoption of this pronouncement did not have any impact on the Company's results of operations or financial condition.

In November 2004, the Financial Accounting Standards Board (FASB) issued SFAS 151, Inventory Costs-- an amendment of ARB No. 43, Chapter 4. This Statement amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Paragraph 5 of ARB 43, Chapter 4, previously stated that ". . . under some circumstances, items such as idle facility expense, excessive spoilage, double freight, and rehandling costs may be so abnormal as to require treatment as current period charges. . . ." This Statement requires that those items be recognized as current-period charges regardless of whether they meet the criterion of "so abnormal." In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. This Statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Management does not believe the adoption of this Statement will have any immediate material impact on the Company. In December 2004, the FASB issued SFAS No.152, "Accounting for Real

Estate Time-Sharing Transactions--an amendment of FASB Statements No. 66 and 67" ("SFAS 152) The amendments made by Statement 152 This Statement amends FASB Statement No. 66, Accounting for Sales of Real Estate, to reference the financial accounting and reporting guidance for real estate time-sharing transactions that is provided in AICPA Statement of Position (SOP) 04-2, Accounting for Real Estate Time-Sharing Transactions. This Statement also amends FASB Statement No. 67, Accounting for Costs and Initial Rental Operations of Real Estate Projects, to state that the guidance for (a) incidental operations and (b) costs incurred to sell real estate projects does not apply to real estate time-sharing transactions. The accounting for those operations and costs

is subject to the guidance in SOP 04-2. This Statement is effective for financial statements for fiscal years beginning after June 15, 2005. with earlier application encouraged. The Company does not anticipate that the implementation of this standard will have a material impact on its financial position, results of operations or cash flows. On December 16, 2004, the Financial Accounting Standards Board ("FASB") published Statement of Financial Accounting Standards No. 123 (Revised 2004), Share-Based Payment ("SFAS 123R").

SFAS 123R requires that compensation cost related to share-based payment transactions be recognized in the financial statements. Share-based payment transactions within the scope of SFAS 123R include stock options, restricted stock plans, performance-based awards, stock appreciation rights, and employee share purchase plans. The provisions of SFAS 123R are effective as of the first interim period that begins after June 15, 2005. Accordingly, the Company will implement the revised standard in the third quarter of fiscal year 2005. Currently, the Company accounts for its share-based payment transactions under the provisions of APB 25, which does not necessarily require the recognition of compensation cost in the financial statements. Management is assessing the implications of this revised standard, which may materially impact the Company's results of operations in the third quarter of fiscal year 2005 and thereafter. On December 16, 2004, FASB issued Statement of Financial Accounting Standards No. 153, Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29, Accounting for Nonmonetary Transactions (" SFAS 153"). This statement amends APB Opinion 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. Under SFAS 153, if a nonmonetary exchange of similar productive assets meets a commercial-substance criterion and fair value is determinable, the transaction must be accounted for at fair value resulting in recognition of any gain or loss. SFAS 153 is effective for nonmonetary transactions in fiscal periods that begin after June 15, 2005. The Company does not anticipate that the implementation of this standard will have a material impact on its financial position, results of operations or cash flows.

ITEM 7. FINANCIAL STATEMENTS

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FINANCIAL STATEMENTS AND SCHEDULES

DECEMBER 31, 2004 AND 2003

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

IR BIOSCIENCES HOLDINGS, INC.

F-1

IR Biosciences Holdings, Inc.

Index to Financial Statements

RUSSELL BEDFORD STEFANOU MIRCHANDANI LLP
CERTIFIED PUBLIC ACCOUNTANTS

REPORT OF INDEPENDENT REGISTERED CERTIFIED PUBLIC ACCOUNTING FIRM

Board of Directors
I R Biosciences Holdings, Inc.
Scottsdale, Arizona

We have audited the accompanying consolidated balance sheets of I R Biosciences Holdings, Inc., development stage company, (the "Company") as of December 31, 2004 and the related consolidated statements of losses, stockholders' equity, and cash flows for the two years December 31, 2004 and 2003 and the period October 30, 2002 (date of inception) through December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based upon our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of IR

Biosciences Holdings, Inc. , a development stage company, as of December 31, 2004 , and the results of its operations and its cash flows for the years ended December 31, 2004 and 2003 and for the period October 30, 2002 (date of inception) through December 31, 2004 , in conformity with accounting principles generally accepted in the United States of America.

/s/ RUSSELL BEDFORD STEFANOU MIRCHANDANI LLP

Russell Bedford Stefanou Mirchandani LLP

New York, New York
March 4, 2005

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

	December 31, 2004
Assets	
Current assets	
Cash and cash equivalents	$ 970,114
Prepaid services and other current assets	6,713
Total current assets	976,827
Licensed proprietary rights, net	7,320
Furniture and equipment, net	6,500
Total assets	$ 990,647
Liabilities and Stockholders' Equity	
Current liabilities	
Current portion of notes payable, net of discount	75,993
Accounts payable and accrued liabilities	307,301
Total current liabilities	383,294
Commitments and Contingencies	
Stockholders' Equity	
Preferred stock, 0.001 par value:	
10,000,000 shares authorized, no shares issued and outstanding	0
Common stock, $0.001 par value; 100,000,000 shares authorized;	
62,423,388 shares issued and outstanding at December 31, 2004	62,423
Additional paid-in capital	7,922,943

Deferred compensation	(169,986)
Deficit accumulated during the Development Stage	(7,208,027)
Total stockholder's equity	607,353
Total liabilities and stockholders' equity	$ 990,647

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

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

	For the Twelve Months Ended December 31, 2004	For the Twelve Months Ended December 31, 2003	Cumulative from Inception (October 30, 2002 to December 31, 2004
Operating expenses:			
Selling, general and administrative expenses	$ 4,498,390	$ 1,045,776	$ 5,589,884
Merger fees and costs	0	350,000	350,000
Financing cost	0	90,000	90,000
Total operating expenses	4,498,390	1,485,776	6,029,884
Operating loss	(4,498,390)	(1,485,776)	(6,029,884)
Other expense:			
Interest expense	807,017	370,926	1,178,143
Total other expense	807,017	370,926	1,178,143
Loss before income taxes	(5,305,407)	(1,856,702)	(7,208,027)
Provision for income taxes	--	--	--
Net loss	$ (5,305,407)	$ (1,856,702)	$ (7,208,027)
Net loss per share - basic and diluted	$ (0.16)	$ (0.09)	$ (0.28)
Weighted average shares outstanding - basic and diluted	33,510,168	21,317,292	25,698,261

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

IR Biosciences Holding, Inc. and Subsidiary
(A Development Stage Company)
Consolidated Statement of
Stockholders' Equity (Deficit) From Date of
Inception (October 30, 2002) to December 31, 2004

	Common Stock		Additional Paid-In	Deferr
	Shares	Amount	Capital	Compensa
Balance at October 30, 2002 (date of inception)	--	$ --	$ --	
Shares of common stock issued at $0.0006 per share to founders for license of proprietary right in December 2002	16,612,276	16,612	(7,362)	
Shares of common stock issued at $0.0006 per share to founders for services rendered in December 2002	1,405,310	1,405	(623)	
Shares of common stock issued at $0.1671 per share to consultants for services rendered in December 2002	53,878	54	8,946	(9
Sale of common stock for cash at $0.1671 per share in December 2002	185,578	186	30,815	
Net loss for the period from inception (October 30, 2002) to December 31, 2002	--	--	--	
Balance at December 31, 2002 (reflective of stock splits)	18,257,042	18,257	31,776	(9
Shares granted to consultants at $0.1392 per share for services rendered in January 2003	98,776	99	13,651	
Sale of shares of common stock for cash at $0.1517 per share in January 2003	329,552	330	49,670	
Shares granted to consultants at $0.1392 per share for services rendered in March 2003	154,450	154	21,346	
Conversion of notes payable to common stock at $0.1392 per share in April 2003	1,436,736	1,437	198,563	
Shares granted to consultants at $0.1413 per share for services rendered in April 2003	14,368	14	2,016	
Sale of shares of common stock for cash at $0.2784 per share in May 2003	17,960	18	4,982	
Sales of shares of common stock for cash at $0.2784 per share in June 2003	35,918	36	9,964	
Conversion of notes payable to common stock at $0.1392 per share in June 2003	718,368	718	99,282	

Beneficial conversion feature associated with notes issued in June 2003	--	--	60,560	
Amortization of deferred compensation	--	--	--	9
Costs of GPN Merger in July 2003	2,368,130	2,368	(123,168)	
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 ended December 31, 2003	--	--	--	
Balance at December 31, 2003	23,431,300	23,431	1,035,441	
Shares granted at $1.00 per share pursuant to the Senior Note Agreement in January 2004	600,000	600	599,400	(600
Shares issued at $1.00 per share to a consultant for services rendered in January 2004	800,000	800	799,200	(800
Shares issued to a consultant at $0.62 per share for services rendered in February 2004	40,000	40	24,760	(24
Shars issued to a consultant at $0.40 per share for services rendered in March 2004	1,051,600	1,051	419,589	(420
Shares issued to a consultant at $0.50 per share for services rendered in March 2004	500,000	500	249,500	(250
Shares sold for cash at $0.15 per share in March, 2004	8,000	8	1,192	
Shares issued at $0.50 per share to consultants for services rendered in March 2004	20,000	20	9,980	
Shares issued to a consultant at $0.40 per share for services rendered in March 2004	2,000	2	798	
Shares issued to consultants at $0.32 per share for services rendered in March 2004	91,600	92	29,220	
Shares to be issued to consultant at $0.41 per share in April 2004 for services to be rendered through March 2005	--	--	--	(82

Shares granted pursuant to the New Senior Note Agreement in April 2004	600,000	600	149,400	(150
Shares issued to officer at $0.32 per share for services rendered in April 2004	200,000	200	63,800	
Conversion of note payable to common stock at $0.10 per share in May 2004	350,000	350	34,650	

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

IR Biosciences Holding, Inc. and Subsidiary
(A Development Stage Company)
Consolidated Statement of
Stockholders' Equity (Deficit) From Date of
Inception (October 30, 2002) to December 31, 2004 (continued)

	Common Stock		Additional Paid-In	Deferr
	Shares	Amount	Capital	Compensa
Beneficial Conversion Feature associated with note payable in May 2004	--	--	35,000	
Issuance of warrants to officers and founder for services rendered in May 2004	--	--	269,208	
Shares to a consultant at $0.20 per share as a due dilligence fee in May 2004	125,000	125	24,875	
Shares issued to a consultant at $1.00 per share for services to be rendered over twelve months beginning May 2004	500,000	500	499,500	(500
Benefial Conversion Feature associated with notes payable issued in June 2004	--	--	3,000	
Issuance of warrants to note holders in April, May, and June 2004	--	--	17,915	
Issuance of warrants to employees and consultants for services rendered in April through June 2004	--	--	8,318	
Shares issued in July to a consultant at $0.10 for services to be rendered through July 2005	250,000	250	24,750	(25
Shares issued to a consultant in July and September at $0.41 per share for services to be rendered through April 2005	200,000	200	81,800	
Shares issued to a consultant in September at				

$0.12 to $0.22 for services rendered through September 2004	127,276	127	16,782	
Shares issued in July to September 2004 as interest on note payable	300,000	300	35,700	
Issuance of warrants with notes payable in July and August 2004	--	--	72,252	
Accrued deferred compensation in August 2004 to a consultant for 100,000 shares at $0.10 per share, committed but unissued	--	--	--	(10
Shares issued in August 2004 at $0.14 to a consultant for services to be performed through October 2004	100,000	100	13,900	(14
Shares issued in August 2004 at $0.125 per share for conversion of $30,000 demand loan	240,000	240	29,760	
Shares issued in August 2004 at $0.16 per share to a consultant for services provided	125,000	125	19,875	
Shares issued to employees at $0.16 to $0.25 per share	48,804	49	8,335	
Commitment to issue 100,000 shares of stock to a consultant at $0.23 per share for services to be provided through September 2005	--	--	--	(23
Sale of stock for cash in Ocober at $0.125 per share, net of costs of $298,155	18,160,000	18,160	1,345,763	
Value of warrants issued with sale of common stock in October, net of costs	--	--	607,922	
Issuance of warrant to officer in October	--	--	112,697	
Issuance of stock to investment bankers in October 2004 for commissions earned	4,900,000	4,900	(4,900)	
Conversion of accounts payable to stock in October at $0.125 per share	1,257,746	1,258	107,382	
Value of warrants issued with accounts payable conversions	--	--	48,579	
Conversion of demand loan to stock in October at $0.11 per share	93,300	93	10,170	
Forgiveness of notes payable in October 2004	--	--	36,785	
Issuance of stock to officer and director at $0.125 per share in October for conversion of liability	1,440,000	1,440	122,493	
Value of warrants issued with officer and director conversion of liabilities	--	--	56,067	
Conversion of debt and accrued interest to common stock at $0.075 to $0.125 per share	6,703,151	6,703	417,514	

Value of warrants issued with conversion of debt	--	--	191,111	
Conversion of note payable in October into common stock at $0.075 per share	67,613	68	4,932	
Issuance of warrants to note holders in October 2004	--	--	112,562	
Value of shares issued to CFO as compensation	100,000	100	34,900	
Value of warrants issued to members of advisory committees in in November and December	--	--	16,348	
Beneficial conversion feature associated with notes payable	--	--	124,709	
Shares issued in error to be cancelled	(9,002)	(9)	9	
Amortization of deferred compensation through December 31, 2004	--	--	--	2,729
Loss for the twelve months ended December 31, 2004	--	--	--	
Balance at December 31, 2004	62,423,388	62,423	7,922,943	(169

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

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

	For the Twelve Months Ended December 31, 2004	For the Twelve Months Ended December 31, 2003	Cum from (Oct 20 Dec
Cash flows from operating activities:			
Net loss	$(5,305,407)	$(1,856,702)	$(7,2
ADJUSTMENTS TO RECONCILE NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:			
Non-cash compensation	3,284,577	114,641	3,4
Interest expense	83,776	68,624	1
Amortization of discount on notes payable	704,633	302,302	1,0
Depreciation and amortization	13,255	12,685	
Changes in operating assets and liabilities:			
Prepaid services and other assets	29,130	(35,842)	

Accounts payable and accrued expenses	148,854	397,402	5
NET CASH USED IN OPERATING ACTIVITIES	(1,041,182)	(996,890)	(2,0
Cash flows from investing activities:			
Acquisition of property and equipment	(4,783)	(3,304)	
NET CASH USED IN INVESTING ACTIVITIES	(4,783)	(3,304)	
Cash flows from financing activities:			
Net proceeds from notes payable	32,500	1,186,000	1,2
Principal payments on notes payable	--	(250,000)	(2
Shares of stock sold for cash	1,973,045	65,000	2,0
Officer repayment of amounts paid on behalf of officer	--	19,880	
Cash paid on behalf of officer	--	(19,880)	(
Cash paid on amount due to officer	--	(22,427)	(
NET CASH PROVIDED BY FINANCING ACTIVITIES	2,005,545	978,573	3,0
Net increase in cash and cash equivalents	959,580	(21,621)	9
Cash and cash equivalents at beginning of period	10,534	32,155	
Cash and cash equivalents at end of period	$ 970,114	$ 10,534	$ 9

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

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

Non-cash investing and financing activities:

	For the Twelve Months Ended December 31, 2004	For the Twelve Months Ended December 31, 2003	Cum from (Oct 20 Dec
Supplemental Disclosures of Cash Flow Information:			
Acquisition and Capital Restructure:			
Assets acquired	$ -	$ -	$
Liabilities assumed	-	(120,799)	
Common stock retained	-	(2,369)	
Adjustment to additional paid in capital	-	123,168	
Organization costs	-	350,000	
Total consideration paid	$ -	$ 350,000	$

Cash paid during the period for interest	$ 54	$ 41,793	$
Cash paid during the period for taxes	$ --	$ --	$
Commmon stock issued in exchange for proprietary rights	$ --	$ --	$
Common stock issued in exchange for services	$ 2,878,006	$ 37,280	$
Common stock issued in exchange for previously incurred debt and accrued interest	$ 695,591	$ 300,000	$
Common stock issued in exchange as interest	$ 36,000	$ --	$
Amortization of beneficial conversion feature	$ 162,709	$ 60,560	$
Stock options and warrants issued in exchange for services rendered	$ 406,571	$ 85,861	$
Debt and accrued interest forgiveness from note holders	$ 36,785	$ --	$
Common stock issued in satisfaction of accounts payable	$ 157,219	$ --	$
Common stock issued in satisfaction of amounts due to an Officer and a Director	$ 180,000	$ --	$

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

IR BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)
NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003
AND FOR THE PERIOD FROM OCTOBER 30, 2002
(INCEPTION) TO DECEMBER 31, 2004

NOTE A - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

Nature of Business

IR Biosciences Holdings Inc. ("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. From its inception through the date of these financial statements, the Company has recognized minimal revenues and has incurred significant operating expenses.

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

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 21,063,170 (post-split) 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 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.

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.

FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003
AND FOR THE PERIOD FROM OCTOBER 30, 2002
(INCEPTION) TO DECEMBER 31, 2004

NOTE A - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Cash and Cash Equivalents

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

Long-lived Assets

The Company has adopted Statement of Financial Accounting Standards No. 144 (SFAS 144). The Statement requires that long-lived assets and certain identifiable intangibles held and used by the Company be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset 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. SFAS No. 144 also requires assets to be disposed of be reported at the lower of the carrying amount or the fair value less costs to sell.

Income Taxes

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

Net Loss Per Common Share

The Company computes earnings per share under Financial Accounting Standard No. 128, "Earnings Per Share" (SFAS 128). Net loss per common share is computed by dividing net loss by the weighted average number of shares of common stock and dilutive common stock equivalents outstanding during the year. Dilutive common stock equivalents consist of shares issuable upon conversion of convertible notes and the exercise of the Company's stock options and warrants (calculated using the treasury stock method). During 2004, 2003 and 2002, common stock equivalents are not considered in the calculation of the weighted average number of common shares outstanding because they would be anti-dilutive, thereby decreasing the net loss per common share.

Liquidity

As shown in the accompanying financial statements, the Company has incurred a net loss of $7,208,027 from its inception through December 31, 2004. The Company's has net working capital of $593,533, with cash and cash equivalents of $970,114 of this amount as of December 31, 2004.

IR BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)
NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003
AND FOR THE PERIOD FROM OCTOBER 30, 2002
(INCEPTION) TO DECEMBER 31, 2004

NOTE A - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Research and Development

The Company accounts for research and development costs in accordance with the Financial Accounting Standards Board's Statement of Financial Accounting Standards No. 2 ("SFAS 2"), "Accounting for Research and Development Costs. Under SFAS 2, all research and development costs must be charged to expense as incurred. Accordingly, internal research and development costs are expensed as incurred. Third-party research and developments costs are expensed when the contracted work has been performed or as milestone results have been achieved. Company-sponsored research and development costs related to both present and future products are expensed in the period incurred. Total expenditures on research and product development for the years 2004, 2003, and the period from October 30, 2002 (date of inception) to December 31, 2004 were $150,091, $42,972 and $193,063, respectively.

Concentrations of Credit Risk

Financial instruments and related items, which potentially subject the Company to concentrations of credit risk, consist primarily of cash, cash equivalents and related party receivables. The Company places its cash and temporary cash investments with credit quality institutions. At times, such investments may be in excess of the FDIC insurance limit. The Company periodically reviews its trade receivables in determining its allowance for doubtful accounts. There is no allowance for doubtful accounts established as of December 31, 2004.

Comprehensive Income

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

Stock Based Compensation

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure-an amendment of SFAS 123." This statement amends SFAS No. 123, "Accounting for Stock-Based Compensation," to provide alternative methods of transition for a voluntary charge to the fair value based

method of accounting for stock-based employee compensation. In addition, this statement amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The Company has chosen to continue to account for stock-based compensation using the intrinsic value method prescribed in APB Opinion No. 25 and related interpretations. Accordingly, compensation expense for stock options is measured as the excess, if any, of the fair market value of the Company's stock at the date of the grant over the exercise

NOTE A - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Stock Based Compensation (continued)

price of the related option. The Company has adopted the annual disclosure provisions of SFAS No. 148 in its financial reports for the year ended December 31, 2004 and 2003 and for subsequent periods. The Company did not issue any stock-based employee compensation during the years ended December 31, 2004 and 2003.

Segment Information

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

Fair Value of Financial Instruments

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

Property and Equipment

Property 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

Website Development Costs

The Company recognizes website development costs in accordance with Emerging Issue Task Force ("EITF") No. 00-02, "Accounting for Website Development Costs." As such, the Company expenses all costs incurred that relate to the planning and post implementation phases of development of its website. Direct costs incurred in the development phase are capitalized and recognized over the estimated useful life of two years. The Company follows the policy of charging costs associated with repair or maintenance for the website to expenses incurred.

Advertising

The Company follows the policy of charging the costs of advertising to expenses incurred. The Company has not incurred any advertising costs during the years ended December 31, 2004 or 2003, or for the period from October 30, 2002 (inception) through December 31, 2004.

NOTE A - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

Reclassifications

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

New Accounting Pronouncements

In November 2004, the Financial Accounting Standards Board (FASB) issued SFAS151, Inventory Costs- an amendment of ARB No. 43, Chapter 4. This Statement amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Paragraph 5 of ARB 43, Chapter 4, previously stated that "under some circumstances, items such as idle facility expense, excessive spoilage, double freight, and rehandling costs may be so abnormal as to require treatment as current period charges" This Statement requires that those items be recognized as current-period charges regardless of whether they meet the criterion of "so abnormal." In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. This Statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. Management does not believe the adoption of this Statement will have any immediate material impact on the Company.

In December 2004, the FASB issued SFAS No.152, "Accounting for Real Estate Time-Sharing Transactions-an amendment of FASB Statements No. 66 and 67" ("SFAS 152) The amendments made by Statement 152. This Statement amends FASB Statement No. 66, Accounting for Sales of Real Estate, to reference the financial accounting and reporting guidance for real estate time-sharing transactions that is provided in AICPA Statement of Position (SOP) 04-2, Accounting for Real Estate Time-Sharing Transactions. This Statement also amends FASB Statement No. 67, Accounting for Costs and Initial Rental Operations of Real Estate Projects, to state that the guidance for (a) incidental operations and (b) costs incurred to sell real estate projects does not apply to real estate time-sharing transactions. The accounting for those operations and costs is subject to the guidance in SOP 04-2. This Statement is effective for financial statements for fiscal years beginning after June 15, 2005. with earlier application encouraged. The Company does not anticipate that the implementation of this standard will have a material impact on its financial position, results of operations or cash flows.

On December 16, 2004, the Financial Accounting Standards Board ("FASB") published Statement of Financial Accounting Standards No. 123 (Revised 2004), Share-Based Payment ("SFAS 123R"). SFAS 123R requires that compensation cost related to share-based payment transactions be recognized in the financial statements. Share-based payment transactions within the scope of SFAS 123R include stock options, restricted stock plans, performance-based awards, stock appreciation rights, and employee share purchase plans. The provisions of SFAS 123R are effective as of the first interim period that begins after June 15, 2005. Accordingly, the Company will implement the revised standard in the third quarter of fiscal year 2005. Currently, the Company accounts for its share-based payment transactions under the provisions of APB 25, which does not necessarily require the recognition of compensation cost in the financial statements. Management is assessing the implications of this revised standard, which may materially impact the Company's results of operations in the third quarter of fiscal year 2005 and thereafter.

On December 16, 2004, FASB issued Statement of Financial Accounting Standards No. 153, Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29, Accounting for Nonmonetary Transactions (" SFAS 153"). This statement amends APB Opinion 29 to eliminate the exception for

NOTE A - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

New Accounting Pronouncements (continued)
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nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. Under SFAS 153, if a nonmonetary exchange of similar productive assets meets a commercial-substance criterion and fair value is determinable, the transaction must be accounted for at fair value resulting in recognition of any gain or loss. SFAS 153 is effective for nonmonetary transactions in fiscal periods that begin after June 15, 2005. The Company does not anticipate that the implementation of this standard will have a material

impact on its financial position, results of operations or cash flows.

NOTE B - PROPERTY, PLANT AND EQUIPMENT

The Company's property and equipment at December 31, 2004 consists of the following:

	2004
Office Equipment	$6,665
Office Fixtures and Furniture	1,423
	8,088
Accumulated Depreciation	(1,588)
	$6,500

Depreciation expense included as a charge to income amounted to $1,078, $510, and $1,588 for the years ended December 31, 2004 and 2003 and from inception to December 31, 2004, respectively.

NOTE C - INTANGIBLE ASSETS

The Company has adopted SFAS No. 142, Goodwill and Other Intangible Assets, whereby the Company periodically tests its intangible assets for impairment. On an annual basis, and when there is reason to suspect that their values have been diminished or impaired, these assets will be tested for impairment, and write-downs to be included in results from operations may be necessary.

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 16,612,276 shares (post-split) of the Company's restricted common, valued at the shares' par value of $0.001 per share, aggregating $ 9,250. These proprietary rights are being amortized over the term of the license agreement, or ten years.

The costs and accumulated amortization of intangible assets at December 31 are summarized as follows:

	2004
Technology License	$9,250
Website	22,500
Less: accumulated amortization	(24,430)
Intangible assets, net	$7,320

Amortization expense included as a charge to income amounted to $12,177 and $12,175 and $24,430 for the years ended December 31, 2004 and 2003, and the period from inception to December 31, 2004, respectively.

NOTE D - ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities at December 31, 2004 are as follows:

	2004
Accounts payable & accrued liabilities	$292,190
Accrued interest	8,946
Accrued payroll and payroll taxes	6,165
Total	$307,301

NOTE E - RELATED-PARTY TRANSACTIONS

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 were on a month-to-month basis. Under the terms of the Consulting Agreements, the Consultants agreed 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 agreed 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. Pursuant to the Consulting Agreements, during the period from January 1, 2003 to December 31, 2003, the Company accrued $120,000 in consulting fees. During the period from January 1, 2004 to December 31, 2004, the Company accrued an additional $90,000 in consulting fees. The amounts due the Consultants at December 31, 2003 was $125,000 and was included in accounts payable and accrued expenses.

In October 2004, the Company achieved the threshold amount of $2,000,000 in equity or debt financing (see Note I). As of October, 2004, the aggregate amounts due the Consultants under the Consulting Agreements was $215,000.

In October, 2004, one of the Consultants elected to exchange 724,000 shares of the Company's common stock and a warrant to purchase an additional 362,000 (post-split) shares of common stock at an exercise price of $0.50 (post-split) in exchange for $90,500 of the $107,500 of the previously accrued and unpaid fees due him under the Consulting Agreement, and the balance of $17,000 was paid to the consultant. At December 31, 2004, there is no balance due to the Consultant.

In October 2004, because the remaining Consultant had not taken an active role in the management of the Company, he agreed that would forgive the amount accrued to him under the Consulting agreement of $107,500. The Company accounted for the transaction as a forgiveness of indebtedness under FAS No. 140 during the period ended December 31, 2004.

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

NOTE E - RELATED-PARTY TRANSACTIONS (CONTINUED)

Proprietary Rights Agreement (continued)

Company will maintain a broad form general liability and product liability insurance (see Note C).

Office Lease

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

In July 2004, the Company leased a new office facility from a third party (see Note J).

InOne Contract

The Company has entered into a series of contracts with InOne Advertising & Design, Inc. ("InOne"). At the time of the initiation of the contracts, InOne employed 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 72,000 shares (post 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 140,000 shares (post 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 20,000 shares (post-split) of the Company's common stock at a price of $0.125; (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 20,000 shares (post-split) of the Company's common stock at a price of $0.125.

At December 31, 2004, InOne no longer employs or has any business relationship with the spouse of the Company's Chief Executive officer, and InOne is no longer considered a related party to the Company.

The amounts due InOne at December 31, 2004 and 2003 are $2,700 and $19,565,

respectively.

Notes payable to related parties at December 31, 2004 consists of the following:

	2004
Promissory notes payable and accrued interest of $12,093 to Company shareholders, interest at 6% per annum, unsecured; The Company is in default under these agreements	$65,993
Less: current portion	(65,993)
	$ --

IR BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY
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NOTE F - NOTES PAYABLE

Notes payable at December 31, 2004 consists of the following:

	2004
Convertible note payable, interest at 8% per annum, due in August 2004; Noteholder has the option, with the consent of the Company, to convert unpaid note principal together with accrued and unpaid interest to the Company's common stock at a price equal to $.835 per share, under certain terms and conditions. In addition, the Company granted the noteholder a warrant to acquire 26,938 shares of the Company's common stock at a price equal to $0.835 per share. The Company is in default under this note agreement.	$ 10,000
Less: current portion	(10,000)
	$ --

At December 31, 2003, the Company had outstanding 17 notes payable in the aggregate amount of $713,171. During the twelve months ended December 31, 2004, the Company entered into 14 other note agreements in the aggregate amount of $575,100. The Company repaid principal in the amount of $572,600 under these notes, and converted principal in the amount of $638,500 plus accrued interest of $57,091 into 7,445,062 shares of common stock. Two of these notes in the aggregate amount of $35,000 plus accrued interest of $1,885 were forgiven for consideration of $100 during the twelve months ended December 31, 2004.

NOTE G - CAPITAL 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, 2004. The company has authorized 100,000,000 shares of common stock, with a par value of $.001 per share. In July, 2003 a one for twenty reverse stock split of the Company's common stock was effected . On April 6, 2004, the Company effected a 2 for 1 forward split of its common stock. Total authorized shares and par value remain the unchanged. Accordingly, the effect of the reverse and subsequent forward split has been presented in the accompanying financial statement and footnote disclosures. As of December 31, 2004, the Company has 62,423,388 shares of common stock issued and outstanding.

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

During the year ended December 31, 2003, the Company issued an aggregate of 267,594 shares of common stock to consultants for services in the amount of $37,280. All valuations of common stock issued for services were based upon the value of the services rendered, which did not differ materially from the fair value of the Company's common stock during the period the services were rendered. In addition, the Company issued 2,155,104 shares of common stock in exchange for $ 300,000 of previously incurred debt. The Company also issued an aggregate of 383,430 shares of common stock in exchange for $ 65,000 net of

NOTE G - CAPITAL STOCK (CONTINUED)

costs and fees. In July, 2003, the Company issued 2,368,130 in connection with the Company's acquisition and merger with GPN Network, Inc. (see Note A.)

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

stock to an officer and a director in satisfaction $180,000 of liabilities.

Private Placement of Common Stock

In October 2004, the Company completed a private placement of its common stock (the "Private Placement") whereby the Company sold an aggregate of $2,450,000 worth of units (each a "Unit" and collectively, the "Units") to accredited investors (as defined by Rule 501 under the Securities Act of 1933, as amended) (the transaction is referred to herein as the "Private Placement"). The Company received proceeds of $1,971,845 after costs of the issuance of $298,155. Included in the $2,450,000 sale was conversion of $180,000 of accrued salary and consulting fees due to an officer and an director of the Company. The number of shares of common stock issued pursuant to the Private Placement was 19,600,000, along with warrants to purchase an additional 9,080,000 shares, plus warrants to purchase an additional 720,000 shares issued to the officer and director. The Company also issued an additional 4,900,000 shares of common stock to its investment banker as commission. The investment bankers did not acquire any warrants pursuant to this transaction.

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

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

(b) a warrant (each a "Warrant" and collectively, the "Warrants") to purchase, at any time prior to the fifth (5th) anniversary following the date of issuance of the Warrant, a number of shares of Common Stock equal to fifty percent (50%) of the number of Shares included within the Unit, at a price equal to fifty cents ($0.50) per share of Common Stock. A form of the Warrant is attached hereto as Exhibit 4.1.

In consideration of the investment, the Company granted to each investor certain registration rights and anti-dilution rights. The Company is obligated to file a registration statement for the shares of common stock issued in the private placement and shares of common stock underlying the warrants issued in the private placement within 30 days of the final closing date of October 26, 2004, or November 25, 2004. The Company is also obligated to effectuate the registration statement within 90 days of the final closing date of October 26, 2004, or January 24, 2005. Failure to meet either of these deadlines results in the Company subject to a penalty of a 2% increase in the number of shares to be registered, or 461,200 shares and warrants to purchase an additional 181,600 shares, for every 30 day period beyond the deadline date. The Company filed a registration statement on November 24, 2004. However, at March 7, 2005, the registration statement has not yet been deemed effective by the Securities and Exchange Commission. Accordingly, at April 3, 2005, the Company has accrued a penalty of two 30-day periods, or 922,400 shares and warrants to purchase an additional 363,200 shares. If the Company fails to complete a registration by April 24, 2005, an additional penalty of 461,200 shares and warrants to purchase 181,600 shares will be incurred.

NOTE G - CAPITAL STOCK

Private Placement of Common Stock (continued)

Also in October 2004, the Company converted certain notes payable with an aggregate principal amount of $573,500 plus accrued interest of $57,091 for a total of $630,328 into Units with terms identical to those provided to investors in the Private Placement. The number of shares of common stock issued via these note conversions was 6,855,062 along with warrants to purchase an additional 3,427,531 shares (see Note H).

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

NOTE H - STOCK OPTIONS AND WARRANTS

Employee Stock Options

The Company has adopted the 2003 Stock Option, Deferred Stock and Restricted Stock Plan (the "Plan") which authorizes the Board of Directors in accordance with the terms of the Plan, among other things, to grant incentive stock options, as defined by Section 422(b) 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 6,465,316 shares . The options will have a term not to exceed ten years from the date of the grant. There have been no options granted under this Plan.

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.

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

Options Outstanding			Options Exercisable		
Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	We Av Exer
$25.00	63,212	5.25	$25.00	63,212	$

Transactions involving stock options issued to employees are summarized as follows:

IR BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY
(A DEVELOPMENT STAGE COMPANY)
NOTES TO FINANCIAL STATEMENTS
FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003
AND FOR THE PERIOD FROM OCTOBER 30, 2002
(INCEPTION) TO DECEMBER 31, 2004

NOTE H - STOCK OPTIONS AND WARRANTS (CONTINUED)

Employee Stock Options (continued)

	Number of Shares	Weighted Average Price Per Share
Outstanding at January 1, 2003	63,212	$25.00
Granted (as restated)	--	
Exercised	--	
Canceled or expired	--	
Outstanding at December 31, 2003	63,212	25.00
Granted	--	
Exercised	--	
Canceled or expired	--	
Outstanding at December 31, 2004	63,212	$25.00

The Company did not issue options to employees during the years ended December 31, 2003 and 2004.

Warrants

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

Warrants Outstanding			Warrants Exercisable		
Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighed Average Exercise Price	Number Exercisable	Weighted Av Remaini Contractua (Year
$0.05-0.10	480,698	4.60	$0.05-0.10	480,698	4.
0.125-0.70	778,511	4.46	0.125-0.70	778,511	4.
0.25-0.56	15,498,021	4.68	0.25-0.56	15,498,021	4.
1.00	741,400	2.98	1.00	741,400	2.
2.00	167,580	4.51	2.00	167,580	4.
	17,666,210	4.59		17,666,210	4.

Transactions involving warrants are summarized as follows:

	Number of Shares (post-split)	Weighted Average Price Per Share (post-split)
Outstanding at January 1, 2003	26,938	$ .84
Granted	805,572	.89
Exercised	--	
Canceled or expired	--	
Outstanding at December 31, 2003	832,510	.89
Granted	16,833,699	.47
Exercised	--	--
Canceled or expired	--	--
Outstanding at December 31, 2004	17,666,210	$ .49

NOTE H - STOCK OPTIONS AND WARRANTS (CONTINUED)

Warrants (continued)

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

	2004	2003
Significant assumptions (weighted-average):		
Risk-free interest rate at grant date	3.75%	2.375%
Expected stock price volatility	163% to 262%	312%
Expected dividend payout	--	--
Expected option life-years (a)	5	5

(a) The expected option life is based on contractual expiration dates.

The amount of the expense charged to operations for compensatory warrants granted in exchange for services was $406,571 and $85,861 during the years ended December 31, 2004 and 2003, respectively.

The Company also capitalized financing costs of $184,814 and $397,394 for warrants granted in connection with placement of convertible debentures for the years ended December 31, 2004 and 2003, respectively. The unamortized financing costs were written off as of December 31, 2003 commensurate with the conversion of the debentures.

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

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

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

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

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

NOTE H - STOCK OPTIONS AND WARRANTS (CONTINUED)

Warrants (continued)

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

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

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

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

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

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

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

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

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

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

the twelve months ended December 31, 2004.

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

NOTE I - COMMITMENTS AND CONTINGENCIES

Office Leases

The Company lease office space under a short term agreement, expiring in September 2005. Rent expense amounted to $31,369 for the years ended December 31, 2003, $41,051 for the year ended December 31, 2004, and $75,154 for the period from October 30, 2002 (inception) through December 31, 2004.

NOTE I - COMMITMENTS AND CONTINGENCIES (CONTINUED)

Employment and Consulting Agreements

The Company has employment agreements with all of its President and Chief Executive Officer. In addition to salary and benefit provisions, the agreements include non-disclosure and confidentiality provisions for the protection of the Company's proprietary information.

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

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.

Litigation

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 and the amount of the judgment is included in accounts payable at December 31, 2004.

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

Obligation to Register Shares

In October 2004, the Company sold shares of its common stock to investors in a private placement transaction. The Company is obligated to file a registration statement for the shares of common stock issued in the private placement and shares of common stock underlying the warrants issued in the private placement within 30 days of the final closing date of October 26, 2004, or November 25, 2004. The Company is also obligated to effectuate the registration statement within 90 days of the final closing date of October 26, 2004, or January 24, 2005. Failure to meet either of these deadlines results in the Company subject to a penalty of a 2% increase in the number of shares to be registered, or 461,200 shares and warrants to purchase an additional 181,600 shares, for every 30 day period beyond the deadline date. The Company filed a registration statement on November 24, 2004. However, at March 7, 2005, the registration statement has not yet been deemed effective by the Securities and Exchange Commission. Accordingly, at April 3, 2005, the Company has accrued a penalty of two 30-day periods, or 922,400 shares and warrants to purchase an additional 363,200 shares. If the Company fails to complete a registration by April 24, 2005, an additional penalty of 461,200 shares and warrants to purchase 181,600 shares will be incurred.

NOTE J - INCOME TAXES

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

NOTE J - INCOME TAXES (CONTINUED)

differences between taxable income reported for financial reporting purposes and income tax purposes are insignificant.

For income tax reporting purposes, the Company's aggregate unused net operating losses approximate $7,200,000 which expire through 2023, subject to limitations of Section 382 of the Internal Revenue Code, as amended. The deferred tax asset related to the carryforward is approximately $2,400,000. The Company has provided a valuation reserve against the full amount of the net operating loss benefit, because in the opinion of management based upon the earning history of the Company, it is more likely than not that the benefits will not be realized.

Components of deferred tax assets as of December 31, 2004 are as follows:

Non Current:	
Net operating loss carryforward	$ 2,400,000
Valuation allowance	(2,400,000)
Net deferred tax asset	$ --

NOTE K - LOSSES PER COMMON SHARE

The following table presents the computations of basic and dilutive loss per share:

	2004	2003	For the Period From October 30, 2002 (Date of Inception) Through December 31, 20
Net loss available to common shareholders	$ (5,305,407)	$ (1,856,702)	$ (7,208,027)
Basic and fully diluted loss per share	$ (0.16)	$ (0.09)	$ (0.28)
Weighted average common shares outstanding	33,510,168	21,317,292	25,698,261

Net loss per share is based upon the weighted average of shares of common stock outstanding. In June , 2003 a .897960946 for one (1) reverse stock split of the Company's common stock was effected (See Note A). Accordingly, all historical weighted average share and per share amounts have been restated to reflect the reverse stock split.

On April 6, 2004, the Company effected a 2 for 1 forward split of its common stock. Accordingly, the effect of the forward split has been presented in the accompanying financial statement and footnote disclosures.

NOTE L - SUBSEQUENT EVENTS

In January, 2005, the Company made a tender offer to temporarily reduce the exercise price of certain warrants issued in October, 2004 from $0.50 to $0.20 per share. The tender offer expired on March 4, 2005. We accepted for exercise a total of 6,600,778 warrants validly tendered and not withdrawn pursuant to the terms of the tender offer, which represents approximately 48% of the aggregate 13,780,449 warrants that were available in the tender offer. The Company raised net proceeds of $1,211,000 via the tender offer.

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

ITEM 8A. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

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

As of the end of the period covered by this Annual Report, we conducted an evaluation, under the supervision and with the participation of our chief executive officer and chief financial officer, of our disclosure controls and procedures (as defined in Rules 13a-15(e) of the Exchange Act). Based on this evaluation, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures need improvement and were not adequately effective as of December 31, 2004 to ensure timely reporting with the Securities and Exchange Commission.

Our management is in the process of identifying deficiencies with respect to our disclosure controls and procedures and implementing corrective measures, which include the establishment of new internal policies related to financial reporting.

Changes in internal controls

There have been no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or 15d-15 under the Exchange Act that occurred during the quarter ended December 31, 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 8B.

Effective December 22, 2004, David T. Harris, Ph.D. resigned from his position as a member of the Board of Directors and as a consultant to ImmuneRegen BioSciences, Inc.

Effective December 22, 2004, Steven J. Scronic resigned from his position as our Corporate Secretary.

Our board of directors appointed Michelle Laroche to serve as our Corporate Secretary, effective as of December 22, 2004. Ms. Laroche joined ImmuneRegen in July of 2003 as Director of Operations. She plays a diverse role in her current position; working on accounting, securities, contracts, and office management. September of 2002 through June of 2003 Ms. Laroche worked within the Credit Department of Mayo Clinic where her main focus was account resolution in preparation for a major software

conversion. From September of 1999 through August of 2002 Ms. Laroche held the position of Executive Assistant at Foresight Capital Corporation where she assisted in all aspects of client relations and office management. There are no family relationships between Ms. Laroche and any of our directors or executive officers. There have been no transactions between Ms. Laroche and the Company or its subsidiary that is required to be reported pursuant to Item 404(a) of Regulation S-B. Ms. Laroche does not have an employment agreement with us.

PART III

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

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

ITEM 10. EXECUTIVE COMPENSATION

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

ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

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

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

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

ITEM 13. EXHIBITS

EXHIBITS

EXHIBIT NUMBER	DESCRIPTION
2.1	Agreement and Plan of Merger dated July 2, 2003 among the Registrant, GPN Acquisition Corporation and ImmuneRegen BioSciences, Inc. (incorporated by reference to exhibit 2 of the Registrant's current report on Form 8-k filed with the Securities and Exchange Commission on July 7, 2003).
3.1	Certificate of Incorporation filed with the Delaware Secretary

	of State on June 4, 1985 (incorporated by reference to exhibit 3.1 of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(a)	Certificate of Amendment filed with the Delaware Secretary of State on July 16, 1987 (incorporated by reference to exhibit 3.1(a) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).

EXHIBIT NUMBER	DESCRIPTION
3.1(b)	Certificate of Amendment filed with the Delaware Secretary of State on February 3, 1992 (incorporated by reference to exhibit 3.1(b) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(c)	Certificate of Amendment filed with the Delaware Secretary of State on November 23, 1992 (incorporated by reference to exhibit 3.1(c) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(d)	Certificate of Amendment filed with the Delaware Secretary of State on December 15, 1994 (incorporated by reference to exhibit 3.1(d) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(e)	Certificate of Amendment filed with the Delaware Secretary of State on November 7, 1995 (incorporated by reference to exhibit 3.1(e) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(f)	Certificate of Amendment filed with the Delaware Secretary of State on December 30, 1996 (incorporated by reference to exhibit 3.1(f) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(g)	Certificate of Amendment filed with the Delaware Secretary of State on November 8, 2000 (incorporated by reference to exhibit 3.1(h) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.2	Amended and Restated Bylaws of the Registrant dated as of January 1, 2002 (incorporated by reference to exhibit 3(b) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
4.1	Specimen Stock Certificate (incorporated by reference to exhibit 4.1 of the Registrant's registration statement on Form

	SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).
4.2	2003 Stock Option, Deferred Stock and Restricted Stock Plan (incorporated by reference to exhibit 4.1 of the Registrant's registration statement on Form S-8 (File No. 333-113511) filed with the Securities and Exchange Commission on March 11, 2004).
4.3	Form of Warrant by and between the Registrant and each of the Investors or Creditors, as the case may be, who entered into an Agreement filed as Exhibit 10.6, 10.7, 10.8 or 10.9 herewith (incorporated by reference to exhibit 4.1 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2004).
4.4	Form of Registration Rights (Annex A to Subscription Agreement) by and between the Registrant and each of the Investors who entered into the Agreements filed as Exhibits 10.6 and 10.8 herewith (incorporated by reference to exhibit 4.2 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2004).
4.5	Form of Anti-Dilution Rights (Annex B to Subscription Agreement) by and between the Registrant and each of the Investors who entered into the Agreements filed as Exhibits 10.6 and 10.8 herewith (incorporated by reference to exhibit 4.3 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2004).
4.6	Promissory Note issued from the Registrant to SBM Certificate Company as of April 28, 2004 (incorporated by reference to exhibit 4.6 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).

EXHIBIT NUMBER	DESCRIPTION
10.1	Employment Agreement dated December 16, 2002 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, and Michael Wilhelm (incorporated by reference to exhibit 10.1 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).
10.2	Consulting Agreement dated December 16, 2002 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, and David Harris (incorporated by reference to exhibit 10.2 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).
10.2(a)	First Amendment to Consulting Agreement dated January 2003 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, and David Harris (incorporated by reference to exhibit 10.2(a) of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and

Exchange Commission on November 24, 2004).

10.3 Consulting Agreement dated December 16, 2002 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, and Mark Witten (incorporated by reference to exhibit 10.3 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).

10.3(a) First Amendment to Consulting Agreement dated January 2003 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, and Mark Witten (incorporated by reference to exhibit 10.3(a) of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).

10.4 License Agreement dated December 16, 2002 among ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, David Harris and Mark Witten (incorporated by reference to exhibit 10.4 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).

10.4(a) First Amendment to License Agreement dated December 20, 2002 among ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, David Harris and Mark Witten (incorporated by reference to exhibit 10.4(a) of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).

10.4(b) Second Amendment to License Agreement dated June 26, 2003 among ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, David Harris and Mark Witten (incorporated by reference to exhibit 10.4(b) of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).

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

10.6 Form of Subscription Agreement entered into as of October 13, 2004 between the Registrant and each of the Investors set forth on the Schedule of Investors thereto (incorporated by reference to exhibit 10.1 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2004).

10.7 Form of Settlement Agreement entered into as of October 13, 2004 between the Registrant and each of the Creditors set forth on the Schedule of Creditors thereto (incorporated by reference to exhibit 10.2 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 19, 2004).

10.8 Form of Subscription Agreement entered into as of October 26, 2004 between the Registrant and each of the Investors set forth on the Schedule of Investors thereto (incorporated by reference to exhibit 10.1 of the Registrant's current report

on Form 8-K filed with the Securities and Exchange Commission on October 27, 2004).

EXHIBIT NUMBER	DESCRIPTION
10.9	Form of Settlement Agreement entered into as of October 26, 2004 between the Registrant and each of the Creditors set forth on the Schedule of Creditors thereto (incorporated by reference to exhibit 10.2 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 27, 2004).
21.1	Subsidiaries of the Registrant (incorporated by reference to exhibit 21.1 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).
23.1	Consent of Russell Bedford Stefanou Mirchandani LLP
31.1	Certification of Chief Executive Officer pursuant to Item 601(b)(31) of Regulation S-B, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Item 601(b)(31) of Regulation S-B, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certifications of Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
32.2	Certifications of Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*

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

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange

Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on April 15, 2005

IR BIOSCIENCES HOLDINGS, INC.

By: /s/ Michael K. Wilhelm

Michael K. Wilhelm
President and Chief Executive Officer

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

SIGNATURE	TITLE	DATE
/s/ Michael K. Wilhelm Michael K. Wilhelm	Chief Executive Officer, President and Director (Principal Executive Officer)	April 19, 2005
/s/ John N. Fermanis John N. Fermanis	Chief Financial Officer (Principal Financial and Accounting Officer)	April 19, 2005
/s/ Theodore E. Staahl Theodore E. Staahl, M.D.	Director	April 19, 2005