

Edgar Filing: IR BIOSCIENCES HOLDINGS INC - Form 10KSB

IR BIOSCIENCES HOLDINGS INC  
Form 10KSB  
March 28, 2006

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, 2005.

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 is not required to file reports pursuant to Section 13  
or Section 15(d) of the Exchange Act. [ ].

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

YES X NO  
-----

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

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

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. [ ]

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

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

The aggregate market value of the Registrant's issued and outstanding shares of common stock held by non-affiliates of the Registrant as of March 24, 2006 (based on the average of the bid and asked prices as reported by the NASD OTC Bulletin Board as of that date) was approximately \$21,208,577.

The number of shares outstanding of Registrant's Common Stock, par value \$0.001 as of March 24, 2006: 69,536,319.

Documents Incorporated by reference: The information required by Part III of Form 10-KSB incorporated by reference from the Registrant's definitive proxy statement on Schedule 14A that will be filed no later than the end of the 120-day period following the Registrant's fiscal yearend, 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  
-----

### TABLE OF CONTENTS

	Page
	----
PART I	
Item 1. Description of Business.....	4
Item 2. Description of Property.....	37
Item 3. Legal Proceedings.....	37
Item 4. Submission of Matters to a Vote of Security Holders.....	37

### PART II

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

Item 5. Market for Registrant's Common Stock, Related Stockholder Matters.....	38
Item 6. Management's Discussion and Analysis or Plan of Operation.....	39
Item 7. Financial Statements.....	F-1 to F-25
Item 8. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.....	48
Item 8A. Controls and Procedures.....	48
Item 8B. Other Information.....	48

### PART III

Item 9. Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act.....	49
Item 10. Executive Compensation.....	50
Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.....	53
Item 12. Certain Relationships and Related Transactions.....	55
Item 13. Exhibits.....	58
Item 14. Principal Accountant Fees and Services.....	63

### FORWARD-LOOKING STATEMENTS

THIS ANNUAL REPORT ON FORM 10-KSB CONTAINS FORWARD-LOOKING STATEMENTS THAT

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

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.

3

### PART I

#### ITEM 1. DESCRIPTION OF BUSINESS

##### 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 potential therapeutics for a number of applications. All therapeutics in development are based on Sar9, Met (02)11-Substance P, an analog of the naturally occurring human neuropeptide Substance P. This neuropeptide can be found throughout the body, including in the airways of humans and many other species. We use the generic name Homsperra to refer to the synthetic Sar9, Met (02)11-Substance P peptide. All of our research and development efforts are early, pre-clinical stage and Homsperra has only undergone exploratory studies to evaluate its biological activity in small animals.

Currently, the majority of our development efforts are centered on two potential therapeutic applications for the active ingredient in Homsperra. Radilex is being formulated specifically for the potential treatment of acute exposure to radiation. Viprovex is being formulated specifically for potential applications relating to the treatment of maladies caused by exposure to various chemical and biological agents. We are currently sponsoring ongoing pre-clinical studies in these areas, specifically two mouse radiation studies on the efficacy of Radilex in treating acute radiation exposure and a rodent study on the efficacy of Viprovex in treating exposure to anthrax. We are designing the protocols for additional radiation studies in mice using Radilex. Additionally, we are designing the protocols for an avian flu study in mice using Viprovex. Both studies have institutions with facilities committed to perform them when, and if, protocols and funding are finalized.

To date we have submitted preliminary study data to the U.S. Food and

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

Drug Administration (FDA) and have been issued two Pre-Investigational New Drug (PIND) numbers, one for the potential use of Radilex in the treatment of acute radiation syndrome and the other for the potential use of Viprovex in the treatment of avian influenza. In addition, we have recently submitted a PIND data package for the use of Viprovex in the potential treatment of chemical exposure. We intend to file final radiation study data from mice with the FDA within six months, and at this time we will request a meeting with the FDA regarding the authorization of a large animal study protocol to test the efficacy of Radilex as a potential treatment for acute radiation syndrome. Also within the next six to twelve months, we plan to submit an Investigational New Drug (IND) application for the potential use of Viprovex in treating Acute Respiratory Distress Syndrome (ARDS).

We have filed patent applications and provisional patent applications, where applicable, in many jurisdictions, inside and outside of the United States, for the use of the active ingredient Sar9, Met (O2)11-Substance P in applications that we are researching. We own two issued U.S. and two issued foreign patents and two pending Patent Cooperation Treaty (PCT) applications, seven pending U.S. provisional patent applications and 16 pending foreign provisional patent applications.

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

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

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

4

### COMPANY HISTORY

We were originally incorporated in the State of Delaware in June 1985 under the name Vocaltech, Inc. to develop, design, manufacture and market products utilizing proprietary speech-generated tactile feedback devices. We completed our initial public offering of our securities in October 1987. In January 1992, we effected a 1-for-6.3 reverse stock split of our common stock. We changed our name to InnoTek, Inc. in November 1992. In December 1994, we

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

acquired all of the outstanding stock of InnoVisions, Inc., a developer and marketer of skin protective products, discontinued our prior operations in their entirety and changed our name to DermaRx Corporation. In April 2000, we effected a reverse merger with a subsidiary of Go Public Network, Inc., which was engaged in assisting early-stage development and emerging growth companies with financial and business development services. We changed our name to GoPublicNow.com, Inc., effected a 1-for-5 reverse stock split and discontinued our prior operations in their entirety. In November 2000, we changed our name to GPN Network, Inc. In July 2001, we discontinued the operations of GPN Network, Inc. in their entirety and began looking for appropriate merger partners. Our objective became the acquisition of an operating company with the potential for growth in exchange for our securities. In July 2003, we effected a reverse merger with ImmuneRegen BioSciences, Inc., adopted our current business model and thereafter changed our name to IR BioSciences Holdings, Inc. In July 2003, we effected a 1-for-20 reverse stock split, and in April 2004, we effected a 2-for-1 stock split. ImmuneRegen BioSciences, Inc. was incorporated in October 2002; all information contained herein refers to the operations of ImmuneRegen BioSciences, Inc., our wholly-owned operational subsidiary.

### RECENT EVENTS

On December 13, 2005 the Board granted 1,000 discretionary incentive stock options to an employee. The options have an exercise price of \$0.31 and a term of five years.

On August 10, 2005, we entered into a new employment agreement with our President and Chief Executive Officer, Michael K. Wilhelm. The employment agreement calls for a salary at the rate of \$275,000 per annum and provides for bonus incentives. Our Board of Directors granted 103,030 discretionary incentive stock options to our Chief Executive Officer, Michael K. Wilhelm, per this new employment agreement. The options have an exercise price of \$0.33 and a term of five years.

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

On May 20, 2005, our Board of Directors granted 150,000 discretionary incentive stock options to our Chief Executive Officer, Michael K. Wilhelm, per his employment agreement. The options have an exercise price of \$0.44 and a term of five years.

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.

On December 9, 2004 we filed for trademarks with US Patent and Trademark Office (USPTO) for Homspira, Radilex and Viprovex. Federal trademark applications are pending. As of the date of this report, no similar registered or pending marks have been found which would bar registration.

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 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 19,600,000 shares of our common stock and warrants to purchase 9,800,000 shares

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

of our common stock. In consideration of the investment, we granted to each investor certain registration rights and anti-dilution rights. We agreed to register these shares along with the shares underlying these warrants within ninety days from the closing date of the transaction, or we would incur a penalty equivalent to an additional 2% of the shares and warrants to be registered for every 30 days that we fail to complete this registration. This penalty amounts to an aggregate of 461,200 shares and 181,600 warrants per 30 day period until such a time as a registration statement that includes these shares and warrants is made effective. As of December 31, 2005, we are required to issue an additional 5,242,307 shares of common stock and warrants to purchase an additional 2,064,187 shares of common stock. At the time these liabilities were incurred, the shares were valued at \$1,991,923 and the warrants were valued at \$638,838. The shares were valued at the market price of the Company's common stock at the time the liabilities were incurred. The warrants were valued utilizing the Black-Scholes valuation model. The aggregate amount of \$2,630,761 was charged to operations as cost of Penalty for late registration of shares during the year ended December 31, 2005.

5

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.

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 \$157,218, we issued to the creditors the following: (a) a number of shares of our common stock determined by dividing the \$157,218 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 \$157,218 claim amount.

Between June 2003 and August 2004 eleven investors entered into fifteen convertible promissory notes totaling \$558,500 with interest rates ranging between 8% and 12% and having various maturities. In October 2004, these notes were converted into equity in the aggregate amount of \$558,500 plus accrued interest of \$56,757. For full and complete satisfaction of debt, we issued to the note holders the following: (a) a number of shares of our common stock determined by dividing the debt amount by an amount between \$0.075 and \$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 October 2004 private placement. Pursuant to the debt conversion we issued an aggregate of 6,694,149 shares of common stock and warrants to purchase 3,347,076 shares of common stock. Under the terms of the conversion agreement, the note holders released us from all claims, known or unknown, relating to the debt amount.

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

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.

Effective December 17, 2004, Eric Hopkins resigned from his position as our Chief Financial Officer. Effective December 22, 2004, our Board of Directors appointed John N. Fermanis to serve as our Chief Financial Officer. Our Board resolved to issue 100,000 shares of registered common stock to Mr. Fermanis for his acceptance of this position. These shares were issued to Mr. Fermanis in May 2005.

Effective December 22, 2004, Dr. Harris resigned from his position as a member of our Board of Directors and a member of the Board of Directors of ImmuneRegen BioSciences, Inc., our subsidiary

Effective December 22, 2004, Steven J. Scronic resigned from his position as our Corporate Secretary. Effective December 22, 2004, our board of directors appointed Michelle R. Laroche to serve as our Corporate Secretary.

### APPLICATIONS IN DEVELOPMENT

#### SUBSTANCE P AND HOMSPERA (Sar9, Met (O2)11-Substance P)

-----

Substance P, discovered in 1931, is a naturally occurring small (1348 D molecular weight) peptide of 11 amino acids that is found throughout the body. Relevant to our current studies, Substance P is localized to the nerves in the airways of many species, including humans. It is believed to be the most potent member of the tachykinin family of neuropeptides, which are widely distributed in the peripheral and central nervous systems and have direct, receptor-mediated actions on most tissues and organs.

In an attempt to find a commercially viable Substance P analog with similar or expanded capabilities, scientists, including our co-founders, Drs. Mark Witten and David Harris, working in the area of Substance P and pulmonary function developed a Substance P analog (Sar9, Met (O2)11-Substance P). In the opinion of management, this compound has been shown to have Neurokinin-1 (NK1) receptor specificity, which has become the basis for our research and development efforts. Homspera is the name by which we refer to the chemical Sar9, Met (O2)11-Substance P in the context of our research and development.

6

#### Radilex and Viprovex

-----

The majority of our development efforts are centered on two drug candidates formulated from Homspera, Radilex and Viprovex. The active ingredient, Homspera, is chemically equivalent in both Radilex and Viprovex. As they are used in differing indications and the formulations and dosing regimens may ultimately also differ, we have created trade names to more easily differentiate the two potential applications with respect to their development and potential future market opportunities. Radilex is the name of the preparation being tested to potentially protect against radiation exposure. Viprovex is the name of the anti-viral preparation for indications to potentially protect against exposure to various chemical and biological agents.



Edgar Filing: IR BIOSCIENCES HOLDINGS INC - Form 10KSB

Chemical Name and Amino Acid Sequence	Generic Name	Trade names for formulations / i
Sar9, Met (O2)11-Substance P	Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Sar-Leu-Met (O2)-NH2	Homspera
		Radilex

Applications

Our potential applications are based on various formulations of Homspera. We currently have potential applications at various stages of pre-clinical development. Our initial pre-clinical applications are in acute radiation syndrome (Radilex) and infectious disease and chemical exposure (Viprovex.)

The basis for our development of potential uses of Homspera is derived from observations made during research funded by the Air Force Office of Scientific Research in early 1994 by our co-founders Dr. Mark Witten and Dr. David Harris. During this research it was observed that the exposure of animals to jet fuel (JP-8) resulted in pathological changes in the lungs and immune systems of those exposed. In the opinion of management, these studies further showed that the administration of Sar9, Met(O2)11-Substance P prevented and reversed the effects of JP-8 jet fuel exposure in the lungs, as well as protected and regenerated the immune system. It is our opinion that, based on the results of these studies, Homspera directly treats the effects of toxic exposure on living cells by inhibiting cell apoptosis (cell-initiated death process). We continue to explore the multiple potential capabilities of Sar9, Met (O2)11-Substance P and to better understand the mechanisms by which this compound can potentially provide protection against gamma radiation, respiratory viruses and various chemical and biological agents.

As traditional efficacy studies would require healthy human volunteers to be exposed to the potentially lethal agents or pathogens, which cannot be done, we intend to apply for approval based upon a new rule adopted by the FDA in 2002, titled "Approval of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible" (Code of Federal Regulations, Title 21, Part 314, Subpart I), which is also referred to as the "animal efficacy rule." Pursuant to this new rule, in situations where it would be unethical to conduct traditional Phase II and Phase III efficacy studies in humans, as is the case with our applications relating to the treatment of maladies caused by exposure to high level gamma radiation and various chemical and biological agents, the FDA will review new drugs for approval on the basis of safety in humans and efficacy in relevant animal models. Through development under this paradigm, management believes near-term development opportunities may exist and development costs are lessened compared to the more traditional drug development model, as Phase II and Phase III of the FDA required drug approval process are not required. Under either scenario, we will not have marketable applications unless and until our drug candidates complete all required safety studies and clinical trials and receive FDA approval in the United States or approval by regulatory agencies outside of the United States.

The table below illustrates our current product candidates and their stage of development within the FDA approval process.

Edgar Filing: IR BIOSCIENCES HOLDINGS INC - Form 10KSB

Product Candidate	Pharmacological Identification	Animal Safety	Pre-Clinical Mechanistic	Phase I	Phase II*	P
Acute Radiation Syndrome						
Radilex	In-progress	Planned	In-progress			
Infectious disease						
Viprovox	In-progress	Planned	In-progress			
Chemical exposure						
Viprovox	In-progress					

\* In development under the animal efficacy rule Phase II and Phase III are potentially not required.

To date we have been issued two Pre-Investigational New Drug (PIND) numbers by the U.S. Food & Drug Administration (FDA) - one for the use of Radilex in the treatment of acute radiation syndrome and one for the use of Viprovox in the treatment of avian influenza. In addition, we have recently submitted a PIND for the use of Viprovox in the treatment of chemical exposure. We expect to file a final radiation study using data collected from our mice studies with the FDA within six months. At this time we will request a meeting regarding the establishment of the protocols necessary for a large animal study to test the efficacy of Radilex as a potential treatment for acute radiation syndrome. Also within the next twelve months, we expect to submit an Investigational New Drug (IND) application for the use of Viprovox in potentially treating Acute Respiratory Distress Syndrome (ARDS).

RADILEX

To date we have sponsored five studies and co-sponsored three radiation studies all of which were conducted utilizing rodents to determine dose response to radiation, the maximum efficacious dose of Radilex, the impact on survival and to distinguish survival response between aerosol delivery versus intra muscular delivery. In each of these studies mice were exposed to varying levels of radiation. In the opinion of management, these studies have demonstrated in C57BL/6 mouse model studies that Radilex-treated mice exhibited survival rates of up to 50% at 90 days post-radiation exposure to an otherwise lethal dose of whole body ionizing radiation. Additionally, it was observed that these mice had normal immune system function at the 90-day post-radiation time point compared to longitudinal control mice. Thus far, in our opinion, the results from our sponsored and co-sponsored rodent studies using Radilex demonstrate efficacy in treating acute radiation syndrome when administered via an inhaler device without requiring any prophylactic treatment. If these results can be reproduced in further studies, including large animal studies, we believe that our treatment could potentially increase an individual's chance of survival in the event of exposure to radiation.

Currently, we are sponsoring additional pre-clinical studies on mice to confirm the potential efficacy of Radilex in treating acute radiation syndrome. In parallel with these studies we are also determining the protocols that we believe will allow us to initiate large animal clinical trials that will be necessary for establishing efficacy per the animal efficacy rule. Assuming adequate funding is available to us, we expect these large animal studies to

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

begin within the next 12 to 18 months. In conjunction with this, we are establishing protocols for toxicology and human safety studies that will also be needed to support a New Drug Application (NDA).

Prior to our formation, initial studies were conducted using Homspira (now Radilex) under the direction of our co-founders, Dr. Mark Witten and Dr. David Harris. These studies are summarized below.

- o Mouse radiation study number one was an initial pilot study using C57BL/6 male mice sponsored by the Air Force Office of Scientific Research (AFOSR). This study was initiated at the University of Arizona College of Medicine, Tucson, Arizona on September 24, 2002. This study attempted to identify an LD50 value, that is, the dose of radiation after which 50% of the mice will die, for subsequent standardization of exposure. The study found that, in the opinion of the lead scientists, the dose rate being delivered in the model system was so great that an LD50 value could not be determined, therefore lower doses were to be explored in subsequent studies.

8

- o Mouse radiation study number two was a pilot study sponsored by the AFOSR. This study was initiated at the University of Arizona College of Medicine, Tucson, Arizona on January 24, 2003. This study lowered the radiation dosage (from 10 Gy to 9 Gy) and administered now Radilex via aerosol administration to determine if the drug had efficacy by increasing survival time from the potentially lethal dose of radiation. The lead scientists believe that this study demonstrated that Radilex treatment after 9 Gy radiation may have efficacy against acute radiation syndrome and that the radiation exposed, Radilex treated mice lived an average of two days longer than untreated, radiation exposed mice.

Our sponsored and co-sponsored studies completed to date, as well as current and planned studies with regard to the development of Radilex are summarized below.

- o Pilot mouse radiation study number 3, co-sponsored by us, was performed at the University of Arizona College of Medicine, Tucson, Arizona, starting on April 10, 2003. The study was intended to determine if Radilex treatment would prolong life in C57BL/6 male mice exposed to a single total body irradiation 7.75 Gy dose of Gamma radiation. In the opinion of management, this study demonstrated that a treatment of a 50 micromolar dose of Radilex kept 25% of the mice alive until 37 days after radiation until the experiment was terminated. The U.S. Food & Drug Administration and the National Cancer Institute utilize a 30-day survival time limit to determine recovery from acute radiation syndrome.
- o Pilot mouse radiation study number 4, co-sponsored by us was initiated at the University of Arizona College of Medicine, Tucson, Arizona on June 16, 2003. This study was conducted to analyze whether higher concentrations of Radilex treatment would prolong life in C57BL/6 male mice exposed to a single total body dose of lethal radiation. In the opinion of management, this study demonstrated that the treatment at the higher concentration level was not efficacious in increasing mouse survival time from a potentially lethal dose of gamma

radiation.

- o Pilot mouse radiation study number 5, sponsored by the AFOSR and co-sponsored by us was initiated at the University of Arizona College of Medicine, Tucson, Arizona on July 11, 2003. This study was designed to confirm radiation lethality and Radilex efficacy of Radilex in preventing lethality in mice. In the opinion of management, this study, replicating pilot radiation mouse study number 3, demonstrated efficacy in increasing mouse survival from a potentially lethal dose of radiation. 50% of radiation-exposed, Radilex-treated mice survived to 90 days post exposure when they were euthanized. Further, in the opinion of management, results of the study showed that when compared with non-irradiated mice, the Radilex-treated, radiation-exposed mice showed no significant differences in their immune system.
- o Pilot mouse radiation study number 6, sponsored by us, was initiated at the University of Arizona College of Medicine, Tucson, Arizona on June 28, 2004. This study was initiated at the request of the US FDA to determine efficacy in treating radiation exposure with Radilex by intramuscular injection, rather than inhalation.

The test subjects consisted of 300 mice separated into three groups of 100. Each group was exposed to different levels of radiation - 7 Gy, 8 Gy (lethal dose) and 9 Gy (lethal dose) - and consisted of 25 male subjects treated with Radilex, 25 female subjects treated with Radilex, and the corresponding control subjects. Each mouse was given a single dose of radiation, and then all non-control mice received a dose of Radilex by direct muscle injection on a daily basis for 60 consecutive days.

In the opinion of management, based on the findings of the study, direct muscle injection was observed to be less effective at similar dosing parameters. We believe this finding may be due to a difference of neurokinin receptors in the lungs of the mice to those in the skeletal muscle, as Radilex is believed to be a neurokinin-1 receptor agonist. Past research has shown the predominant neurokinin receptor in the lungs is the neurokinin-1 receptor, whereas, the predominant neurokinin receptor in rodent skeletal muscle was demonstrated to be the neurokinin-2 receptor.

9

Furthermore, while conducting this study, scientists believe that they witnessed potential wound healing properties of Radilex. During the testing, some of the subjects developed open wounds from natural causes. At the end of the 60-day study, the injuries of the control group remained, while the wounds of the Radilex treated mice had healed. We have filed a provisional patent for the use of Radilex in the promotion of wound healing. If additional funding becomes available in the future, we may look to further study this potential use of Radilex.

- o Pilot mouse radiation study number 7, sponsored by ImmuneRegen, was initiated at the University of Arizona College of Medicine, Tucson, Arizona on November 20, 2004.

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

This study was intended to find a maximum efficacious dose of Homospira in mice exposed to total body 7.75 Gy dose of Gamma radiation. All mice remained alive until 17 days post exposure, when they were exposed to a second dose of radiation, at 9 Gy. All of the mice died at roughly the same time. In the opinion of management, this study may have been confounded by the fact that the mice spent their first 7 days post-exposure in Biolevel 2 conditions which maintains a lower bacterial load, masking the immunocompromised subjects' vulnerability to elements that would impact study results.

- o A blood profile study sponsored by us was conducted at the University of Arizona College of Medicine, Tucson, Arizona beginning on August 25, 2005. This was an exploratory pilot study to demonstrate protection of C57BL/6 mice from neutropenia and thrombocytopenia (decreases in systemic neutrophils and platelets, respectively) and lethality following a single dosage of gamma radiation of 8.25 Gy. In the opinion of management, efficacy was demonstrated, as the treated mice trended toward restored blood and platelet cell numbers with normalized pathology of bone marrow compared to the control group. Although the study demonstrated efficacy, we were unable to demonstrate mechanistic effects due to an inability to collect enough blood for adequate study.
- o On January 9, 2006, based on these studies and other pre-clinical observations, we sponsored a radiation sensitivity animal model study using C57BL/6 mice at the University of Arizona College of Medicine, Tucson. We designed this radiation study to further the proof of concept for the formulation of Sar9, Met (O2)11-Substance P with either a TFA salt or HCl salt. We expect this study to be completed by April 2006.
- o We have finalized the protocols for what we believe will be our final phase of rodent studies. Based on these protocols we are currently sponsoring a radiation study on mice. This study commenced on February 28, 2006 and is being conducted at Oak Ridge National Laboratory. This study was designed to follow the AFRRRI model for radiation sickness. The purpose of this study is to provide confirmation evidence supporting the efficacy of Radilex as a treatment to a lethal dose of radiation exposure. Several factors are being evaluated in this study, including dosage, route of administration, and the need for, and extent of, required pretreatment. In our opinion, if these studies are deemed successfully completed, under the current animal efficacy rule, we will qualify to move to studies in large animals. We estimate the initial study of this phase of rodent studies will be concluded within 90 days of initiation at a cost of approximately \$90,000.

On January 14, 2004, we received a Pre-Investigational New Drug Application (PIND) number for the use of Radilex (PIND No. 63,255) in the treatment of acute radiation syndrome. We are currently inserting new data and summarizing recent study results. We expect to file an updated PIND submission for the use of Radilex in the treatment of acute radiation syndrome with this new data to the FDA's Department of Counterterrorism within the next 120 days. If desirable results are achieved, we anticipate filing the results of the Oak Ridge National Laboratory study with the FDA's Department of Counterterrorism within the next 6 to 9 months. At such time, we would request a meeting with the FDA to establish a protocol for a Radilex study on primates.

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

### VIPROVEX

We are also researching the efficacy of Viprovex as a potential treatment for exposure to various chemical agents, including formalin, and biological agents, including influenza and anthrax, as well as a potential treatment for acute respiratory distress syndrome (ARDS). Based on past research, the active ingredient in Viprovex (Sar9, Met (O2)11-Substance P), in the opinion of management, plays an important role during early responses of the lungs to various substances, including, what we believe to be a blocking of the inflammatory cascade that potentially leads to the destruction of lung tissue.

10

To date, we have only conducted limited preclinical studies with regard to the development of Viprovex. In the opinion of management, preliminary results from pilot studies reveal the potential effects of Viprovex on the immune system, including protection and replenishment, increased cytokines (TNF(alpha), interferon-gamma) that reflect system activation, enhanced phagocytotic activity, potential dendritic cell/T cell activation, inhibition of apoptosis and increased T cell mitogenesis. It is the opinion of management that these results may underlie the potential ability of Viprovex to enhance flu therapies, minimize the respiratory impact of influenza infection and augment the capability of vaccination to induce a protective immune response.

Prior to our formation, initial studies were conducted using Homspera (now Viprovex) under the direction of our co-founder and Director, Dr. Mark Witten. These studies were the basis for our research and development efforts. A series of initial studies were conducted on the efficacy of Homspera (now Viprovex) in treating JP-8 jet fuel induced immunotoxicity in mice. Mice were administered a dose of JP-8 jet fuel to develop a chemically-induced AIDS with the near total destruction of all immune system cells. In the opinion of management, aerosol treatment with Viprovex directly stimulated the production of immune system cells which remained viable after Viprovex treatment.

Pilot studies to date and current studies with regard to the development of Viprovex are summarized below.

- o In September 2003, a third party pilot study was conducted at the University of Arizona, Arizona Health Sciences Center, Lung Injury Laboratory using Homspera (now Viprovex) as a potential treatment for mice infected with the LP-BM5 murine leukemia retrovirus. In the mice infected with the LP-BM5 murine leukemia retrovirus, it is the opinion of management that Viprovex treatment caused a seven-fold increase in spleen interferon-gamma production and a significant increase in spleen T-cell mitogenesis. Based on these findings, it is the opinion of management that the administration of exogenous interferon-gamma has potential efficacy, suggesting that increased endogenous production may enhance protection against some respiratory viruses.
- o In October 2003 the AFOSR sponsored preliminary studies with the Hong Kong influenza virus (A/Hong Kong/8/68) at the University of Arizona, Arizona Health Sciences Center, Lung Injury Laboratory. These studies demonstrated, in the opinion of management, that in mice exposed to the irritant JP-8 jet fuel and then inoculated with the Hong Kong respiratory virus (HKV), the elevated levels of inflammatory cells in their lungs were reduced in animals also treated with Viprovex. In contrast to hydrocarbon-weakened control animals exposed to the virus, animals also treated with Viprovex did not develop

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

the clinical symptoms of viral infection, the increases in alveolar macrophages and neutrophils in broncho-alveolar lavage fluid, and the loss of ciliated epithelium (the latter as determined by electron microscopy). Treated animals also had lower levels of leukotriene B4 than animals not treated with Viprovex. Elevated LTB4 would attract the inflammatory cells, particularly neutrophils, which would follow infection with virus. Electron micrographs showed no virus particles in the Viprovex-treated animals, in contrast to the HKV/JP-8 controls, suggesting, in our opinion, that Viprovex actually prevented viral replication and pathology, perhaps by stimulating the pulmonary alveolar macrophages to actively phagocytose the virus more effectively. Without virions in the lungs, there would be no need to mount an immune response.

Based on the results of this study, it is the opinion of management that Viprovex may be used to enable the body's own immune system to naturally fight off flu strains. Thereby, opening up the possibility that Viprovex could be used either as a stand alone treatment or as an adjunct to a vaccine or other therapy. Further, based on the results from this study we are pursuing government and military collaborations to test Viprovex on treating avian influenza (H5N1).

- o We co-sponsored an asthma pilot study in February, 2005 initiated at the University of Arizona by Dr. Mark Witten. The pilot study was to determine if Viprovex is effaceable in blocking the development of airway hyperactivity. Twenty-three male C57BL/6 mice, seven of which were controls, were exposed to cigarette/cigar smoke to induce an "asthma-like" bronchoconstrictive condition. The mice were divided into cigar or cigarette smoking groups and half of each received a daily aerosol treatment of Viprovex. Dr. Witten then administered one hour smoke exposure for five days a week for three consecutive weeks. In the opinion of management, the results indicated that Viprovex treatments could be utilized to attenuate the development of airway hyperactivity after toxic exposure to either cigarette or cigar smoke.

11

- o A third party formalin pilot study in rats was initiated at the University of Arizona College of Medicine, Tucson, Arizona sponsored by Dr. Witten on August 22, 2005. This study was designed to determine if aerosolized Viprovex would be efficacious in attenuating lung injury after chemical (formalin) exposure. The data collected from the study was given to us by Dr. Witten and, in the opinion of management, indicates that Viprovex treatment before formalin exposure to the lungs greatly attenuated the lung injury normally induced by formalin as evidenced by electron micrographs and lethality. Based on these results, as additional research and development funding is made available to us we plan to conduct additional studies on the use of Viprovex as a treatment for chemical exposure, to include chemicals such as formalin and ricin.
- o We are sponsoring a series of studies with Hyperion Biotechnology Inc. at their laboratory facilities located at Brooks City-Base in San Antonio, Texas with the cooperation of the U.S. Air Force School of Aerospace Medicine (USAFSAM). We

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

designed these studies based on our opinion that Viprovex may block the inflammatory cascade that can lead to the destruction of lung tissue and our conjecture that Viprovex may have a similar effect on combating exposure to anthrax spores.

These studies are being conducted in hope of determining the efficacy of Viprovex in treating exposure to anthrax bacilli. The purpose of these studies is to determine if Viprovex will reduce the mortality rate of an active infection of pulmonary anthrax. These tests will also look for efficacy of Viprovex as a preventive to pulmonary anthrax sickness.

The first of these studies was initiated in October 2005. Logistical considerations related to number of animals requiring exposure and performance of a full Viprovex dose-response curve within specified time limits following anthrax exposure required the experiment be performed in two sections, and it is incomplete at this time. The second half of the full dose-ranging experiment began in February, 2006.

On November 29, 2005 we applied for a PIND from the Department of Health and Human Services (HHS) for the use of Viprovex in the treatment of avian influenza. The PIND number for the use of Viprovex in treating avian flu was issued on December 19, 2005 (PIND No. 73,709). We expect to continue to investigate the efficacy of Viprovex in the treatment of avian influenza, with the goal of submitting an application for an IND under the animal efficacy rule within the next 12 to 18 months.

Based on the results of this formalin pilot study in rats, we applied for a PIND from the HHS for the use of Viprovex in treating chemical exposure on November 28, 2005. As we await PIND status, we intend to plan additional studies to further our research and development activities as it relates to this indication.

Based on data from early initial and subsequent studies indicating the potential use of Viprovex in treating chemically induced ARDS, we plan to submit an IND application to the FDA for the treatment of the effects of ARDS using Viprovex within the next 12 to 18 months.

Due to our liquidity and limited cash available our spending on research and development activities in 2004 and 2005 was limited. We spent approximately \$113,731 and \$150,091 in 2005 and 2004, respectively, in research and development activities related to the development of Radilex and Viprovex as protectants against the effects of chemical, biological, radiological and nuclear threats. From our inception in October 2002, we have spent \$306,794 in research and development activities. These costs only include the manufacture and delivery of our drug by third party manufacturers and payments to Contract Research Organizations for consulting related to our studies and costs of performing such studies. Significant costs relating to research and development, such as consulting fees for Drs. Witten and Siegel among others, have been classified in consulting fees for consistency of financial reporting.

If we are successful in obtaining additional funding through grants or investment capital, we anticipate that during the next 12 months we will increase our research and development spending to a total of approximately \$3,500,000 in an effort to further develop Radilex and Viprovex. This research and development cost estimate includes a radiation study on large animals, which we estimate will cost up to \$2,500,000 depending on the choice of contractor, additional animal pharmacology studies, formulation and animal safety/toxicity studies, as well as, small pilot pharmacological studies exploring possible additional indications. If we are unable to raise additional capital, our



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

research and development activities may be lessened.

12

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

### POTENTIAL FUTURE PIPELINE APPLICATIONS

During our research and development efforts, we may, from time to time, observe results that may lead to other potential applications using Homspera. At the time of such an observation, we may design studies to further evaluate the use for the indication. If these further studies support our initial observations, we may file provisional patent applications for the use of Homspera with the hope of protecting future development rights until we have the ability to design additional studies and protocols and perform research with regard to such applications.

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

### DEVELOPMENT PROGRAM

#### Use of Contract Research Organizations (CRO)

-----

It is understood that extensive time and money is spent developing new drug applications by the time they are approved by required regulatory agencies for use on the market. In order to efficiently and expeditiously navigate the research, development and regulatory approval process in hopes of bringing our applications to market, our development program relies on the use of Contract Research Organizations (CRO's).

CRO's are independent laboratories, registered with the FDA, that provide contract services to the pharmaceutical industry. These CRO's offer broad therapeutic expertise, advanced technologies and extensive resources for drug discovery and drug and device development, and in some instances partnering opportunities. In the opinion of management, using these outside organizations helps to maximize our flexibility and minimize our one-time costs in outsourcing very expensive programs to those companies that maintain the necessary infrastructure to perform these cost-effectively according to internationally recognized standards. Further, as product demands change, we believe that this structure will allow us to move our resources to more appropriate contract

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

research or development or formulation or manufacturing facilities without incurring loss of time or money on outdated projects and programs. As we move our candidate products into FDA-compliant animal safety testing, we expect to contract with specialty groups, organizations or companies that meet regulatory requirements and have adequate and appropriate technical capabilities, rather than develop and maintain an animal use and care facility ourselves that is compliant with current Good Laboratory Practices.

In September, 2003, we contracted with Synergos, Inc. of The Woodlands, Texas, a CRO, to represent us in all FDA communications and to contact and interact with the FDA on our behalf. Likewise, in October, 2003 we contracted with Huntingdon Life Sciences of East Millstone, New Jersey to conduct a two week inhalation toxicity study of Homspera in rats. Further studies on analytical techniques, toxicology and formulation of Homspera were conducted by AppTec Laboratory Services of San Jose, California starting in November, 2003 through August, 2005.

### GRANTS

From time to time, we may apply for governmental grants and respond to formal requests from the government for additional information, thereby possibly allowing us to be included as a candidate for potential future grants. The submission of grants by us is summarized below.

In May, 2003 we applied for a grant with the Department of Health and Human Services (DHHS), solicitation Number 266-01-SARS, Treatment from the National Institute of Allergy and Infectious Diseases. The agency was seeking potential treatments for the SARS virus infection. Our proposal called for \$771,000 to research Viprovex (then Homspera) as a potential treatment for SARS. Our application for grant funding was not accepted.

13

On September 20, 2004 we submitted a grant application to the DHHS in response to its Request for Application (RFA) entitled Biodefense Countermeasure Development: Project Bioshield. Our proposal called for \$1,500,000 to study Radilex (then Homspera) as a countermeasure for radiation exposure. Our application for grant funding was not accepted.

In October 2004, the DHHS released a Request for Information (RFI) regarding potential therapeutics for the treatment for acute radiation syndrome, entitled Therapeutics to Treat Neutropenia and Thrombocytopenia associated with Acute radiation Syndrome. We notified the DHHS of our intent to submit in December 2004. In June 2005, the terms of the RFI were changed by the DHHS and a Request for Proposal (RFP) was issued. Although we intended to apply for the RFP, no proposal was submitted as we believed that our technology did not meet the specific criteria under the new terms of the RFP.

On March 11, 2005, we submitted a final response to an invitation to participate in the Canadian Defense Ministry's "Universal Protectants Proposal" respective to the use of Radilex for potentially treating the negative effects of acute radiation syndrome and/or other health threats, such as anthrax, that may result from chemical, biological, radiological and nuclear (CBRN) terrorist threats. The goal of this program was to find a "universal" treatment for these CBRN threats. The proposal is under the auspices of the Ottawa and Suffield provincial branches of the Canadian Defense Ministry's research and development program, the CBRN Research and Technology Initiative. We responded to this initiative as we believe Radilex may have the potential to be a candidate as a universal protectant against maladies caused by chemical, biological, radiological and nuclear (CBRN) attacks. We are led to this conclusion because in management's opinion the methods of action of Radilex do not simply

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

neutralize the attacking agent, but actually increase immune system activity, thereby allowing the body's own immune system to attack and overcome the CBRN agent. This program was abandoned by the Canadian government for budgetary reasons prior to the acceptance of any companies into the study.

On October 11, 2005 we submitted a grant proposal for the US Army Research Office's Broad Agency Announcement (BAA) W911NF-05-R-0011. The purpose of the BAA was to develop new technologies for the Department of Defense's Chemical and Biological Defense Transformational Medical Technologies Initiative Fund. We signed a letter of intent with Battelle Laboratories Medical Research and Evaluation Facility in West Jefferson, Ohio to conduct the Bio-level III containment studies with Viprovex and avian influenza if our proposal is accepted. The amount of funding sought in the grant proposal was approximately \$1,000,000. Our application for grant funding was not accepted.

On January 6, 2006, we applied for a grant offered by the Defense Threat Reduction Agency (DTRA), solicitation number DTRA01-06-BAA-01. The objective of our grant proposal, entitled "Advanced Proteomic Analysis of Putative Universal Protectant Mechanisms of a Biologically Active Synthetic Peptide," is: (i) to identify biomarkers for further defining our previous observations relating to Radilex/Viprovex-modulated resistance to chemical, biological and radiological stress and (ii) developing a model of mechanistic pathways for potential chemical, biological and radiological injury protection. We have entered into an agreement with Pacific Northwest National Laboratory (PNNL) for this research if our application is accepted. The research involved would be performed through the National Institute of Health (NIH)-funded Proteomics Research Resource of Integrative Biology at PNNL. The funding sought for this grant application is \$2,325,000. As of March 20, 2006, the awarding of the grants is still pending.

On January 31, 2006 we submitted a response to sources sought notice W9113M-06-S-0002 issued by the Department of Defense (DoD). The purpose of this announcement was to identify companies that believe they have a viable candidate for drugs that can be expeditiously developed and will provide a safe and effective countermeasure against radiation injury. We are anticipating a formal RFP to be issued by the DoD. As of March 20, 2006, an RFP is still pending.

On February 7, 2006 we submitted a grant proposal to the Defense Advanced Research Projects Agency's (DARPA) Broad Agency Announcement (BAA) BAA-05-19. The purpose of the BAA was to develop new technologies for DARPA's Defense Science Office (DSO) program. The specific aim for us in this grant was the development of defense against weapons of mass destruction: technologies to render biological, chemical, nuclear, or radiation attacks against the U.S. military harmless. More specifically, we focused on medical countermeasures against both known and unknown pathogens and infectious disease, accelerated manufacture of biologics, including vaccines and immune modifiers, and medical countermeasures against radiation exposure. We proposed collaboration with Pacific Northwest National Laboratory (PNNL) in Richland, Washington in which studies would be conducted to explore the mechanism of Sar(9), Met (02)(11)-Substance P to mitigate or prevent mortality/morbidity resulting from exposure to inhaled viruses, chemical toxicants and whole body radiation. Through multiplexed cytokine analysis and evaluation of the proteomic modifications induced by Sar(9), Met (02)(11)-Substance P, we hoped to identify common pathogenesis pathways for use of our compound as a universal protectant. Our application for grant funding was not accepted.

Correspondence with the Food and Drug Administration (FDA), National Institute of Health (NIH) and other government agencies

The following is a chronological summary of our correspondence with the U.S. Food and Drug Administration (FDA), the National Institutes of Health (NIH)

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

and other government agencies.

On October 16, 2003, Jennifer L. Wike of Synergos, Inc., our Contract Research Organization (CRO), spoke with Sandy Barnes, FDA Project Manager. Ms. Barnes inquired as to whether our ARDS Pre-IND meeting package was ready to be sent to the FDA. Further, she informed us that she had put ImmuneRegen on their meeting agenda for two possible dates in November 2003. Twelve copies of the meeting information package were subsequently sent to the FDA by the Company.

14

On October 30, 2003, Jennifer L. Wike returned a call to Dr. Ray Anthracite, FDA Medical Reviewer. Dr. Anthracite had called to further inquire about the amino acid comprising the structure of Sar9, Met (O2)11-Substance P. Dr. Anthracite confirmed that he is the medical reviewer for our potential product; however, he could not confirm a date for the Pre-IND teleconference. He did state that the agency had an internal meeting for our potential product set for November 5, 2003.

On November 4, 2003, Jaye Thompson, Ph.D. of Synergos, Inc. received a call from Cheryl Turner of the FDA Division of Counterterrorism (DCT). Ms. Turner stated that the division wanted to have an introductory call with the Company. A date of November 17, 2003 at 2:00PM EST was selected. We were informed that Mary Purucker, MD, Division Director, DCT would be present for the meeting and that despite the delays in contacting us, her division was interested in the potential of Sar9, Met (O2)11-Substance P for treating acute radiation syndrome (ARS).

On November 17, 2003 we and regulatory consultants from Synergos, Inc. engaged in a teleconference with representatives from the FDA's Division of Counterterrorism (DCT) to discuss the development of Homspera for use in the event of a radiological terrorist event. Although the counterterrorism group could not comment upon the specifics of the planned studies, they indicated that development of this product would be regulated according to the provisions of the animal efficacy rule. They also indicated that, with submission of appropriate toxicity data, the selected animal model would be acceptable.

On January 14, 2004, we received a communication from Ryan Barraco, FDA Consumer Safety Officer via facsimile confirming a meeting date of March 12, 2004 at 1:30PM EST in Rockville, MD in relation to a Pre-IND meeting to discuss Homspera and the potential of a derivative to have potential efficacy in the treatment of acute radiation syndrome. The confirmation also stated that the agency required receipt of 33 hard copies and one disk of the company's background package no later than February 13, 2004.

Also on January 14, 2004 the company received a fax from Cheryl Turner, FDA Division of Counter-Terrorism with a summary of the Pre-IND meeting that was held on November 17, 2003 to determine the appropriate division for submitting "Homspera for Treatment of Acute Radiation Syndrome (ARS)."

On February 18, 2004 our Pre-IND 63,255 (Treatment of ARS) Meeting Package was sent to Ryan Barraco of the FDA for use in the corresponding meeting set for March 12, 2004.

On March 12, 2004, we met with representatives of the FDA regarding Radilex to discuss pre-clinical studies that will need to be completed prior to submission of a marketing application, other requirements for product approval and the study design of the proposed post-marketing study. The representatives from the FDA suggested that we perform additional studies using specific guidelines, i.e. number of mice, gender of mice, range of radiation dosage and additional potential methods of administration. The representatives also

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

suggested that the company develop a "response team" that can be rapidly deployed to an incident site to help in implementation, conduct and data acquisition of the proposed study.

On October 21, 2004 Dr. Helen Quill of the National Institute of Health (NIH) contacted us to request that Homspera's mechanisms of action were needed in conjunction with a Request for Information (RFI) submission. These were subsequently electronically sent to Dr. Quill on November 1, 2004.

On January 11, 2005, we received a meeting confirmation from Ryan Barraco, FDA Consumer Safety Officer via fax. A meeting date of February 17, 2005 at 11:30AM EST in Rockville, MD was set in relation to Pre-IND 63,255 for Radilex (Homspera). The confirmation letter also stated that the agency required receipt of 18 hard copies and one electronic copy of our background package no later than January 20, 2005.

15

On February 15, 2005 we received a fax from Ryan Barraco, FDA Consumer Safety Officer, regarding responses from the FDA to our questions in the background package.

On February 22, 2005 our representatives met with members of the NIH to discuss: the potential use of Viprovex in an anthrax model; conducting further studies under an AFRRRI model using Radilex for a treatment for acute radiation syndrome; as well as, additional pharmacokinetic and dose-timing research.

On July 1, 2005 Mui Erkun, Director of Procurement, Department of Homeland Security (DHS), contacted us to request a meeting regarding our potential therapeutics with interest in assisting the company with communication to government officials and or agencies.

On September 6, 2005 Michael Wilhelm, our CEO, and Dr. Hal Siegel, our Director of Product Development and Regulatory Affairs met with the Department of Homeland Security in Washington, DC. They met with Drs. Vitko and Pilai in order to discuss our potential therapeutics and efficacy. Also discussed was our request for support. Both doctors indicated interest, but mentioned that until the Chief Medical Officer, Jeff Runge, took office with DHS the office would only be focused on consequence management involving logistical preparation and detection, not therapeutics.

On September 21, 2005 Michael Wilhelm, Dr. Hal Siegel and Dr. Mark Witten presented to Armed Forces Radiobiology Research Institute (AFRRRI) at their offices in Bethesda, Maryland. They presented their findings of possible efficacy in treating acute radiation syndrome with Radilex. We mentioned that we have used survival as an end point to the lethal exposure in our studies. Further, we reported our observations that we believe that the best form of administration of our potential therapeutic is via inhalation. AFRRRI researchers confirmed that a study using the preexisting AFRRRI rodent radiation model as a guide needs to be completed.

On December 19, 2005 we received a letter via US Mail from the Department of Health and Human Services (DHHS) thanking us for our Avian Flu Pre-IND Submission. A Pre-IND number was assigned (73,709). The letter stated that a panel of experts is further reviewing our submission and will assemble a letter with comments/advice to be sent out to us within the next several weeks.

### COLLABORATORS AND CONTRACTORS

We have fostered and managed relationships with other laboratories

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

working in related areas of research and government agencies who are interested in learning more of our applications, and perhaps helping to bring them to commercialization. Collaborators and Contractors who we have already worked with or are implementing a program are described below.

- o We have sponsored or co-sponsored six mouse radiation studies and co-sponsored one inhalation study at the University of Arizona College of Medicine, Tucson, Arizona since January, 2005. Additionally, we are currently sponsoring a radiation study which began on January 9, 2006. In addition, the Air Force Office of Scientific Research, AFOSR, has sponsored additional studies at the University of Arizona College of Medicine utilizing Homspera Radilex and Viprovex.
- o Hyperion Biotechnology Inc. performs research programs in the areas of probiotics, biomarker discovery, infectious disease and human performance enhancement. We have contracted a series of anthrax studies with Hyperion testing Viprovex as a treatment to anthrax infection. These studies are conducted by Hyperion at its research facility located on the U.S. Air Force School of Aerospace Medicine (USAFSAM) campus in Brooks City-Base in San Antonio, Texas.
- o St. Joseph's Hospital and Medical Center (Phoenix, Arizona) has performed assays on Homspera for us on a sub-contracting basis.
- o Battelle Memorial Institute's Medical Research and Evaluation Facility (MREF) (Columbus, Ohio) has issued a letter of intent to support us in our testing of Homspera as an Avian Influenza therapeutic in mice. The letter of intent was included in a grant application we submitted to the Army Research Office in October, 2005 in response to their Broad Agency Announcement Grant # W911NF-05-R-0010 for therapeutics against bio-terrorism.

16

- o Pacific Northwest National Laboratory (Redmond, Washington) has issued a letter of intent to support us in our testing of Homspera as a Universal Protectant therapeutic. The letter of intent was included in a grant application we submitted to the Defense Threat Reduction Agency (DTRA) in January, 2006 in response to their Broad Agency Announcement, Grant # DTRA01-06-BAA-01 for therapeutics against bio-terrorism.
- o We have contracted with Oak Ridge National Laboratory (Oak Ridge, Tennessee) to conduct Proof of Concept mouse radiation studies that began in February, 2006 and to help facilitate additional pre-clinical and future clinical trials with regard to determining the potential efficacy of Radilex as a treatment for acute radiation syndrome.

### ADVISORY BOARDS AND CONSULTANTS

To assist us in the research and development of our various applications we make use of outside consultants and advisory boards.

#### Consultants

We currently contract three outside consultants related to the research and

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

development, including regulatory affairs, of our potential products.

Hal Siegel, Ph.D., through his consulting company, Siegel Consultancy, provides strategic and tactical expertise to life science companies, helping them meet FDA requirements from pre-clinical studies through the regulatory submission process and into the post-approval marketplace. He has over a decade of experience delivering scientific, clinical and regulatory compliance assistance as well as submission preparation and management services to life sciences client companies developing drugs, therapeutic biologics, combination products, traditional devices and in vitro diagnostic products. His degrees are from Rensselaer Polytechnic Institute and SUNY Buffalo (Ph.D., Biochemical Pharmacology). Our contract with Siegel Consultancy, signed on March 16, 2005, calls for the consultant to provide initial and ongoing product development, quality control compliance, regulatory consulting and submission preparation as needed. Compensation is at an hourly rate and includes reimbursement for travel and documented expenses. There is no set termination date with this contract.

Kelly McQueen, MD, MPH, PLLC was engaged on July 29, 2005 for a term of three months to provide comprehensive public health consulting and act as liaison with United States military services to pursue collaborative research in the area of infectious diseases and upper respiratory illnesses. Kelly McQueen is a practicing anesthesiologist and public health consultant in Phoenix, Arizona. She currently works with the United States (U.S.) Army and the US Northern Combatant Command on Infectious Disease, Disaster Planning and other public health projects. She also teaches infectious disease threat management and treatment for the International Committee for the Red Cross (ICRS) course on Health Emergencies in Large Populations (HELP). Ms. McQueen's contract with us provides for cash compensation on an hourly basis and reimbursement for travel and expenses. We have mutually agreed to extend the contract at the same terms on a month by month basis.

Dr. Jack Caravelli, Ph.D. was contracted on November 5, 2005 to provide advisory services in support of ImmuneRegen's initiative to commercialize radiation sickness treatments, bio-defense applications and countermeasures. He is presently a senior Advisor for the Threat Reduction Cooperation with the Office of Policy at the U.S. Department of Energy (D.O.E.). Dr. Caravelli's contract calls for cash compensation at an hourly rate and reimbursement for any related travel and expenses. The initial contract had a term of two months and we have mutually agreed to extend the contract at the same terms on a month by month basis.

### Advisory Board

-----

We currently have three advisory boards: Drug Development, Oncology & Dermatology and Bioterrorism Preparedness. Advisory board members are appointed for one-year terms by our management. For services rendered, members of our advisory boards are compensated on a quarterly basis in common stock purchase warrants.

The Drug Development and Oncology & Dermatology Boards were formed to educate and provide direction with regard to the development of applications using Homspera in the areas of expertise of the various advisory board members.

The following individuals comprise our Drug Development Advisory Board:

Moshe Arditi, M.D., Senior Advisor: Director, Division of Pediatric Infectious Diseases, Cedars-Sinai Medical Center, Los Angeles, CA,

Mr. Ralph Di Libero, Associate Advisor: Vice President, European Sales and Marketing, PolyPeptide Laboratories A/S in Denmark

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

K.A. Kelly McQueen, M.D., MPH, Associate Advisor: Anesthesiologist and Public Health Consultant; Infectious Disease and Disaster Planning for U.S. Army and US Northern Combatant Command

17

Hal Siegel, Ph.D., Associate Advisor: Principal and Founder, Scientific, Clinical, and Regulatory Compliance, Siegel Consulting

Simon Wong, M.D., MPH, Associate Advisor: Research Assistant Professor, University of Arizona Health Science Center, Department of Pediatrics.

The following individuals comprise our Oncology & Dermatology Advisory Board:

Dr. John Dann, M.D., D.D.S., Senior Advisor

Dr. Jeffery Friedman, M.D., Senior Advisor: Diplomat, American Board of Cosmetic Surgery, American Board of Otolaryngology Head and Neck Surgery, Fellow of the American Academy of Cosmetic Surgery

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

The Bioterrorism Preparedness Advisory Board, was formed at the suggestion of the U.S. Food and Drug Administration's (FDA) Division of Counterterrorism (DCT) to develop a "response team" that can be rapidly deployed to an incident site in the event of a biological or radiological attack to help in implementation, conduct and data acquisition. As there are several first responder teams already in place, we opted to concentrate on forming a group to discuss logistics and coordination between agencies and these first responder groups in the event of an attack. We have attempted to appoint knowledgeable military and private citizens that possess first hand experience in combat casualty and mass trauma scenarios, including preparation for a bioterrorist attack and/or medical or scientific expertise. The following individuals comprise our Bioterrorism Preparedness Advisory Board:

James R. Campbell, PhD, M.P.H, Senior Advisor: Commanding Officer of the Office of Naval Research Global, United States NAVY, Medical Corps, (Ret.), Manager for Biosecurity and Biodefense, in the National Security Directorate at the Pacific Northwest National Laboratory.

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

Dennis E. Amundson, D.O., Senior Advisor: Captain, United States Navy, Medical Corps, Naval Medical Center, San Diego, Pulmonary Medicine

Moshe Arditi, M.D., Senior Advisor: Director, Division of Pediatric Infectious Diseases, Cedars-Sinai Medical Center, Los Angeles, CA

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

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

Mr. Ralph Di Libero, Associate Advisor: Former-Vice President, European Sales and Marketing, PolyPeptide Laboratories A/S in Denmark



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

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

Col. Kerrie Lindberg (Ret.), Associate Advisor: Colonel, USAF, Nurse Corps, (Ret.), Former Director, Defense Institute for Medical Operations (DIMO), Brooks City-Base, Texas

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

Additionally, as part of the process of researching a deployment plan and keeping the Bioterrorism Preparedness Advisory Board current with recent events, our management has met with several congressional leaders responsible for legislation relating to Homeland Security, including the office of Senator Joseph Lieberman and the office of House Representative J.D. Hayworth to have the opportunity to ascertain their viewpoints on emerging preparedness. Additionally, in February 2005, management met with the New York State Office of Public/Homeland Security (NYSOPS), the agency responsible for detection, identification, response, prevention and recovery for a terrorist act or threat in New York State.

### MANUFACTURING

Management expects that Radilex and Viprovex will ultimately have distinct formulations and dosing regimens, however, at this early stage of development, the formulations used are identical. We do not have, and do not intend to establish, manufacturing facilities to produce Homspera, Radilex or Viprovex or any potential products, if any, derived from Homspera. We have used and expect to continue to use third party manufacturers to obtain synthetic Sar9, Met (O2)11-Substance P. We believe Sar9, Met (O2)11-Substance P is readily available at low cost from several life science and technology companies that

18

provide biochemical and organic chemical products used in scientific and genomic research, biotechnology, pharmaceutical development and the diagnosis of disease and chemical manufacturing. Further, we believe that the Sar9, Met (O2)11-Substance P is readily available from various sources, and several suppliers are capable of supplying such in both clinical and initial commercial quality and quantities.

To date, we have acquired Sar9, Met (O2)11-Substance P (Homspera), which is the active ingredient in experimental formulations of Radilex and Viprovex from three different manufacturers. These are Sigma Aldrich, Inc. of Dallas Texas, PolyPeptide Laboratories A/S of Hillerod, Denmark and C S Bio Company Inc. of Menlo Park, California. Since we are only purchasing research quantities of the drug at this time, we have not entered into any contracts or agreements with any third party manufacturers, other than standard non-disclosure agreements.

The manufacture of Radilex, Viprovex or any potential products, if any, derived from Homspera, whether done by outside contractors, as planned, or internally, will be subject to rigorous regulations, including the need to comply with the FDA's current Good Manufacturing Practice (cGMP) standards. As part of obtaining FDA approval for each product, each of the manufacturing facilities must be inspected, approved by and registered with the FDA. In addition to obtaining FDA approval of the prospective manufacturer's quality control and manufacturing procedures, domestic and foreign manufacturing

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

facilities are subject to periodic inspection by the FDA and/or foreign regulatory authorities.

### PATENTS AND PROPRIETARY RIGHTS

Patents and other proprietary rights are essential to our business. We file patent applications to protect our technologies, inventions, and improvements to our inventions that we consider important to the development of our business. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

The active ingredient in Homspera, Radilex and Viprovex is the compound Sar9, Met (O2)11-Substance P. The intellectual property owned by us, as further described below, is for the various potential uses of Sar9, Met (O2)11-Substance P. Additionally, we are in the process of pursuing several other use patent applications based on the use of Homspera.

We currently hold issued patents in the U.S. for use of Sar9, Met (O2)11-Substance P, the active ingredient in Homspera, Radilex, and Viprovex for inhibiting tumor growth and/or metastasis in cancer patients and for stimulating the immune system of immunocompromised individuals such as Acute Radiation Syndrome victims. Similar patent rights are held in Europe and Australia. In the latter two regions, we also have been issued patent rights for use of the active ingredient in Homspera, Radilex and Viprovex for stimulating the maturation of a juvenile immune system, for stimulating an immune response to a viral or bacterial infection, and for reducing the risk of cancer.

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

The following is a list of the registered patents and provisional patent applications in our portfolio. All of the inventor rights for all patents and all patent applications listed have been assigned to us by the inventors, Dr. Mark Witten and/or Dr. David Harris. Some of our research has been or is being funded by the Air Force Office of Scientific Research and has been or is being conducted at the University of Arizona. We have received waivers of rights to the invention from the United States Air Force and the University of Arizona in regard to patent and patent applications for Substance P Treatment for Immunostimulation. We are expecting to receive similar waivers from the United States Air Force and the University of Arizona for the remaining patent applications in our intellectual property portfolio. In total, our patent portfolio consists of two issued U.S. and two issued foreign patents and two pending Patent Cooperation Treaty (PCT) applications, seven pending U.S. applications and 16 pending foreign patent applications. The assignment documents are included as Exhibits.

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

### Registered Patents:

Title	Serial No.
Substance P Treatment for Immunostimulation for Immunostimulation US 5,998,376 Australia 737201	US 5,945,508 Substance P Treatment for Immunostimulation European 0957930

### PATENTS PENDING:

Title	Serial No.
Acute Respiratory Syndromes	US 10/553232
Acute Respiratory Syndromes	Europe (Application number TBA)
Acute Respiratory Syndromes	Singapore (Application number TBA)
Acute Respiratory Syndromes	Vietnam 1-2005-015
Amelioration of Effects of Cigarette Smoke	US 10/645,839
Amelioration of Effects of Cigarette Smoke	Singapore 2005 01072-3
Amelioration of Effects of Cigarette Smoke	Vietnam 1-2005-00215
Amelioration of Effects of Cigarette Smoke	Japan 2004-532943
Amelioration of Effects of Cigarette Smoke	European Union 3791722.6
Amelioration of Effects of Cigarette Smoke	Canada -2496447
Anti-Aging Effects of Substance P	PCT/US05/13113
Inducing and Maintaining Hair Color	PCT/US05/13112
Method to Promote Wound Healing	US 60/622,015
Prevention of Respiratory Diseases in Fowl	US 60/641153
Prevention of Respiratory Diseases in Fowl	Singapore 200500467-6
Prevention of Respiratory Infection in Fowl	Vietnam 1-2005-00599
Prevention of Respiratory Infection in Fowl	Thailand 097659
Stimulation of Hair Growth	US 10/539/734
Substance P Treatment for Immunostimulation	Canada 2,261,885
Treatment of Asthma	US 60/667,062
Treatment of Asthma	Singapore 200504104-1
Treatment of Skin Diseases	US 60/642,996
Treatment of Skin Diseases	Vietnam 1-2005-00598
Treatment of Skin Diseases	Thailand 098080
Treatment of Skin Diseases	Singapore 200500466-8

Our rights to the US Patent Nos. 5,945,508 and 5,998,376, Substance P Treatment for Immunostimulation, have certain limitations with respect to the University of Arizona and the United States Air Force as described below. If patents are issued for any of our pending patent applications, the same limitations would most likely apply.

Our agreements with the University of Arizona outline very specific rights in regard to our sponsored-supported projects. In accordance with our sponsored-supported project agreements, the University of Arizona retains the right to use data developed during these projects for non-commercial purposes, including teaching, research and education. ImmuneRegen BioSciences, Inc. retains the rights to trade secrets, inventions, developments and discoveries as limited by the University of Arizona's employment contracts in effect at the time the intellectual property was created. Further to this point, the principal investigator at the University of Arizona, Dr. Mark Witten, was a consultant to ImmuneRegen BioSciences, and, under the terms of his consulting agreement, ImmuneRegen BioSciences, Inc. retains rights to any developments or discoveries that he made in the course of working for us.

As a result of governmental funding, the U.S. Government has certain

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

rights in the technology developed with such funds. These rights include a non-exclusive, paid-up, worldwide license under such inventions for any governmental purpose. In addition, the government has the right to require us to grant an exclusive license under any of such inventions to a third party if the government determines that: (i) adequate steps have not been taken to commercialize such inventions, (ii) such action is necessary to meet public health or safety needs, or (iii) such action is necessary to meet requirements for public use under federal regulations.

In this regard, the United States Air Force has reserved a non-exclusive license to the patents (US Patent Nos. 5,945,508 and 5,998,376) in connection with Air Force grant F49620-94-1-0297 and may, under certain conditions, have commensurate or additional license rights under the Bayh-Dole Act. Those rights are set forth in 35 USC 202(c)(4) and 37 CFR 401.9 and 14(a).

Under the federal Bayh Dole Act, a party which acquires an exclusive license for an invention that was partially funded by a federal research grant is subject to the following government rights: (i) products using the invention which are sold in the U.S. are to be manufactured substantially in the U.S. unless a waiver is obtained; (ii) the government may force the granting of a license to a third party who will make and sell the needed product if the licensee does not pursue reasonable commercialization of a needed product using the invention; and (iii) the U.S. Government may use the invention for its own needs.

20

Moreover, besides the rights that have been granted to the U.S. Government, the validity and breadth of claims in medical technology patents involve complex legal and factual questions and, therefore, may be highly uncertain. No assurance can be given that any patents based on pending patent applications or any future patent applications by us will be issued, that the scope of any patent protection will exclude competitors or provide competitive advantages to us, that any of the patents that have been or may be issued to us will be held valid if subsequently challenged or that others will not claim rights in or ownership of the patents and other proprietary rights held by us. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of our products or design around any patents that have been or may be issued to us. Since patent applications in the U.S. are maintained in secrecy until shortly before a patent's issuance, we also cannot be certain that others did not first file applications for inventions covered by our pending patent applications, nor can we be certain that we will not infringe any patents that may be issued to others on such applications.

We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements. It is our policy to require our employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific limited circumstances. We also require signed confidentiality or material transfer agreements from any company that is to receive our confidential information. In the case of employees, consultants and contractors, the agreements generally provide that all inventions conceived by the individual while rendering services to us shall be assigned to us as our exclusive property. There can be no assurance, however, that these agreements

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

will not be breached, that we would have adequate remedies for any breach, or that our trade secrets or unpatentable know-how will not otherwise become known or be independently developed by competitors.

Our potential success will also depend in part on our ability to develop commercially viable products without infringing the proprietary rights of others. We have not conducted freedom of use patent searches and no assurance can be given that patents do not exist or could not be filed which would have an adverse affect on our ability to market our products or maintain our competitive position with respect to our products. If our technology components, devices, designs, products, processes or other subject matter are claimed under other existing U.S. or foreign patents, or are otherwise protected by third party proprietary rights, we may be subject to infringement actions. In such event, we may challenge the validity of such patents or other proprietary rights or we may be required to obtain licenses from such companies in order to develop, manufacture or market our products. There can be no assurances that we would be able to obtain such licenses or that such licenses, if available, could be obtained on commercially reasonable terms. Furthermore, the failure to either develop a commercially viable alternative or obtain such licenses could result in delays in marketing our proposed products or the inability to proceed with the development, manufacture or sale of products requiring such licenses, which could have a material adverse affect on our business, financial condition and results of operations. If we are required to defend ourselves against charges of patent infringement or to protect our proprietary rights against third parties, substantial costs will be incurred regardless of whether we are successful. Such proceedings are typically protracted with no certainty of success. An adverse outcome could subject us to significant liabilities to third parties and force us to curtail or cease our development and sale of our products and processes.

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

### RESEARCH AND LICENSE AGREEMENTS

Our patents and continued research on Sar9, Met (O2)11-Substance P are derived from discoveries made during research studies funded by the Air Force Office of Scientific Research in early 1994 by our Director, Dr. Mark Witten. In December 2002 we entered into consulting agreements on a month-to-month basis with Dr. Mark Witten and Dr. David Harris, who are our two founders and largest shareholders. Under the terms of these agreements, Drs. Witten and Harris agree to place at the disposal of us their judgment and expertise in the area of acute lung injury. In consideration for these services, we agreed to pay each of Drs. Witten and Harris a non-refundable fee of \$5,000 per month. We and Dr. Harris agreed to terminate the consulting agreement for Dr. Harris in March 2005. In January 2006, the company received correspondence from Dr. Witten stating that he would terminate his consulting contract if his specific requirements were not met. We subsequently accepted his termination effective February 1, 2006.

In December 2002, we entered into a royalty-free license agreement with Drs. Witten and Harris. Under the terms of the license agreement, Drs. Harris and Witten granted to us an exclusive license to use and sublicense certain patents, medical applications, and other technologies developed by them. Our

obligations under this agreement include (i) reasonable efforts to protect any

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

licensed patents or other associated property rights; (ii) reasonable efforts to maintain confidentiality of any proprietary information; (iii) upon the granting by the U. S. Food and Drug Administration to us the right to market a product, we will, for so long as we sell any product or medical application which incorporates or utilizes the patents, medical applications, and other technologies developed by Drs. Witten and Harris, maintain in full force and effect policies of general liability insurance (with Broad Form General Liability and Product Liability endorsements) with limits of not less than \$1,000,000 per occurrence and \$1,000,000 annual aggregate. The license agreement will terminate ten years after the date of the expiration of the last patent issued or issuing with respect to the licensed patents, medical applications, and other technologies. The resignation of Dr. Harris as a director of our company in December 2004 and as a consultant in March 2005 does not have any impact upon the terms of the license agreement. The resignation of Dr. Witten as a consultant to our company in February 2006 does not have any impact upon the terms of the license agreement.

In February 2005, Drs. Witten and Harris executed assignment documents in which, for good and valuable consideration, patent applications and patents developed by them were assigned to ImmuneRegen BioSciences, Inc. The assignment documents included all of the patents and patent applications which were included in and covered by the Licensing Agreement, as amended. Drs. Witten and Harris have also assigned all proprietary technology developed at ImmuneRegen subsequent to the execution of the February 2005 assignment documents.

### GOVERNMENTAL REGULATION

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

### REGULATORY PROCESS IN THE UNITED STATES

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

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

Regardless of how our product candidates are regulated, the FFDCA and other Federal statutes and regulations govern or influence the research,

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

testing, manufacture, safety, labeling, storage, record-keeping, approval, distribution, use, product reporting, advertising and promotion of such products. Noncompliance with applicable requirements can result in civil penalties, recall, injunction or seizure of products, refusal of the government to approve or clear product approval applications or to allow us to enter into government supply contracts, withdrawal of previously approved applications and criminal prosecution.

### PRODUCT APPROVAL IN THE UNITED STATES

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

22

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:

- o completion of pre-clinical laboratory tests or trials and formulation studies;
- o submission to the FDA of an IND for a new drug or biologic, which must become effective before human clinical trials may begin;
- o 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,
- o submission and approval of a New Drug Application, or NDA, for a drug, or a Biologics License Application, or BLA, for a biologic.

Pre-clinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity. The results

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

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:

- o assess its efficacy in specific, targeted indications;
- o assess dosage tolerance and optimal dosage; and,
- o identify possible adverse effects and safety risks.

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

As described above, for several of the product opportunities we are pursuing, we may apply for approval based upon a new rule adopted by the FDA in 2002, titled "Approval of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible" (Code of Federal Regulations, Title 21, Part 314, Subpart I), which is also referred to as the "animal efficacy rule." Pursuant to this new rule, in situations where it would be unethical to conduct traditional Phase II and Phase III efficacy studies in humans, as is the case with our applications relating to the treatment of maladies caused by exposure to various chemical and biological agents, the FDA will review new drugs for approval on the basis of safety in humans and efficacy in relevant animal models.

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

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



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

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

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

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.

24

Manufacturers are also subject to various state and Federal laws and regulations governing laboratory practices (specifically, the requirement for certain studies to comply with current Good Laboratory Practices), the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances in connection with their research. In each of the above areas, the FDA has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products and deny or withdraw approvals.

Some of our drug candidates may need to be administered using specialized drug delivery systems. We may rely on drug delivery systems that are already approved to deliver drugs like ours to similar physiological sites or, in some instances, we may need to modify the design or labeling of the legally available device for delivery of our product candidate. In such an event, the FDA may regulate the product as a combination product or require additional approvals or clearances for the modified device. Further, to the extent the delivery device is owned by another company, we would need that company's cooperation to implement the necessary changes to the device and to obtain any additional approvals or clearances. Obtaining such additional approvals or clearances, and cooperation of other companies, when necessary, could significantly delay, and increase the cost of obtaining, marketing approval, which could reduce the commercial viability of a drug candidate.

### HIPAA REQUIREMENTS

Other federal legislation may affect our ability to obtain certain health information in conjunction with our research activities. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, mandates, among other things, the adoption of standards designed to safeguard the privacy and security of individually identifiable health information. In relevant part, the U.S. Department of Health and Human Services, or HHS, has released two rules to date mandating the use of new standards with respect to such health information. The first rule imposes new standards relating to the privacy of individually identifiable health information. These standards restrict the manner and circumstances under which covered entities may use and disclose protected health information so as to protect the privacy of that information. The second rule

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

released by HHS establishes minimum standards for the security of electronic health information. While we do not believe we are directly regulated as a covered entity under HIPAA, the HIPAA standards impose requirements on covered entities conducting research activities regarding the use and disclosure of individually identifiable health information collected in the course of conducting the research. As a result, unless they meet these HIPAA requirements, covered entities conducting clinical trials for us may not be able to share with us any results from clinical trials that include such health information.

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

### SECURITIES LAWS

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

### DISTRIBUTION

If Radilex or Viprovex receives approval from the FDA, we will attempt to commercialize these applications. Upon such approval, if Radilex we intend to use our best efforts to market it as a treatment to the damaging effects of radiation injury that result after exposure to total body irradiation. If Viprovex, we intend to use our best efforts to market it as a medical countermeasure to the effects of exposure to various biological and chemical agents. We intend to offer for sale these applications to various governmental agencies at the local, state and federal levels, both domestically and potentially outside the United States.

Prior to FDA approval, Radilex and Viprovex 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 our studies, in the opinion of management, indicate that Radilex may have efficacy in the treatment of the life-threatening effects of radiation exposure and Viprovex to exposure to various biological and chemical agents, we believe there may be interest by government agencies to stockpile Radilex and/or Viprovex if it is successfully developed. However, there is no assurance that any of such orders will be forthcoming and we have received no indication from Project BioShield or any other agency that it intends to

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

purchase any quantities of Radilex or Viprovex.

### COMPETITIVE ENVIRONMENT

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

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

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

We believe that due to the global political environment that time to market is critical in the discovery of an effective countermeasure to radiation exposure and other biological and chemical threats. New developments in areas in which we are conducting our research and development are expected to continue at a rapid pace in both industry and academia. It is due to these reasons that we believe that competition will be driven by time to market.

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

### EMPLOYEES

From our inception through the period ended December 31, 2005, we have relied on the services of outside consultants for services and currently have five total employees, two contract employees and three full-time employees. Our full-time employees are Michael K. Wilhelm, our Chief Executive Officer; John Fermanis, our Chief Financial Officer; and, the third serves in an administrative role. In order for us to attract and retain quality personnel, we

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

anticipate we will have to offer competitive salaries to future employees. We do not anticipate our employment base will significantly change during the next twelve months, 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 costs for personnel. This projected increase in personnel is dependent upon our generating revenues and obtaining sources of financing. There is no guarantee that we will be successful in raising the funds required or generating revenues sufficient to fund the projected increase in the number of employees.

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

26

### RISK FACTORS

IN EVALUATING OUR BUSINESS, YOU SHOULD CONSIDER THE FOLLOWING DISCUSSIONS OF RISKS, IN ADDITION TO OTHER INFORMATION CONTAINED IN THIS REPORT AS WELL AS OUR OTHER PUBLIC FILINGS WITH THE SECURITIES AND EXCHANGE COMMISSION. ANY OF THE FOLLOWING RISKS COULD MATERIALLY ADVERSELY AFFECT OUR BUSINESS, FINANCIAL CONDITION, RESULTS OF OPERATIONS AND PROSPECTS.

#### RISKS RELATED TO OUR FINANCIAL RESULTS

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

As of December 31, 2005, we had a working capital deficit of \$2,273,444. This amount consists of cash of \$265,860 and current assets of \$24,507, accounts payable of \$243,703, accrued current liabilities of \$258,426 and an accrued current liability of \$2,061,683 related to a penalty for the late registration of the securities sold in our October 2004 private placement. We anticipate settling this late registration penalty in additional shares of common stock and warrants to purchase additional shares of common stock. If this non-cash liability were to be removed from our working capital position as of December 31, 2005, we would have a working capital deficit of \$211,761. We have incurred a substantial net loss for the period from our inception in October 2002 to December 31, 2005, and are currently experiencing negative cash flow. We expect to continue to experience negative cash flow and operating losses through at least 2009 and possibly thereafter. As a result, we will need to generate significant revenues to achieve profitability.

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

We are focused on product development and have not generated any revenue to date. We do not believe we will begin earning revenues from operations until the calendar year 2009 as we transition from a development stage company. We have incurred operating losses since our inception. Our net loss for the fiscal year ended December 31, 2005 was \$4,591,107. As of December 31, 2005, we had an accumulated deficit of \$11,799,134.

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

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

Our independent certified public accountants have stated in their report included in this Form 10-KSB that the Company has incurred a net loss and negative cash flows from operations of \$4,591,107 and \$1,884,113, respectively, for the year ended December 31, 2005, and a lack of operational history, among other matters, that raise substantial doubt about its ability to continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. The effect of this going concern would materially and adversely affect our ability to raise capital, our relationship with potential suppliers and customers, and have other unforeseen effects.

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

Based on our current plans, we believe our existing financial resources, and interest earned thereon, will be sufficient to meet our operating expenses and capital requirements through March 2006. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. We estimate that we will require approximately \$5 million over the next 12 months in order to finance our research and development efforts, fund operating expenses, pursue regulatory clearances and prosecute and defend our intellectual property rights. We may seek such additional funding through public or private financing or through collaborative arrangements with strategic partners.

You should be aware that in the future:

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

If we cannot raise additional funds when needed, or on acceptable terms, we will not be able to continue to develop our drug candidates. We require substantial working capital to fund our operations. Since we do not expect to generate significant revenues in the foreseeable future, in order to fund operations, we will be completely dependent on additional debt and equity financing arrangements. There is no assurance that any financing will be sufficient to fund our capital expenditures, working capital and other cash requirements beyond March 2006. Our working capital deficit as of December 31, 2005 was \$211,761 net of the accrual of securities pursuant to the penalty

27

provision of our October 2004 private placement. No assurance can be given that any such additional funding will be available or that, if available, can be obtained on terms favorable to us. If we are unable to raise needed funds on acceptable terms, we will not be able to develop or enhance our products, take advantage of any future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, we will not be able to continue operations.

WE HAVE DEFERRED, AND MAY CONTINUE TO DEFER, PAYMENT OF SOME OF OUR OBLIGATIONS,

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

WHICH MAY ADVERSELY AFFECT OUR ABILITY TO OBTAIN GOODS AND SERVICES IN THE FUTURE.

We estimate that we will require approximately \$5 million to meet our expenses for the next 12 months. Until such time, if at all, as we receive adequate funding, we intend to defer payment of all of our obligations that are capable of being deferred. Such deferment has resulted in the past, and may result in the future, in some vendors demanding cash payment for their goods and services in advance, and other vendors refusing to continue to do business with us, which may adversely affect our ability to obtain goods and services in the future, or to do so on favorable terms.

WE WILL NEED TO CONDUCT SIGNIFICANT ADDITIONAL RESEARCH, PRECLINICAL TESTING AND CLINICAL TESTING AND EXPECT TO INCUR LOSSES AS WE RESEARCH, DEVELOP AND SEEK REGULATORY APPROVALS FOR OUR POTENTIAL PRODUCTS.

All of our research and development efforts are early, pre-clinical stage and Homspera has only undergone exploratory studies to evaluate its biological activity in small animals. We will need to conduct significant additional research, pre-clinical testing and clinical testing before we can file applications with the FDA for approval of our product candidates. To date we have not yet made applications with the FDA or any other governmental regulatory agency for approval for our drug candidates, nor have we been in a position to seek such approval. Until such time as we are able to file a New Drug Application (NDA), and it is subsequently approved, we will not be able to market or manufacture any products.

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

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

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

### RISKS RELATED TO OUR BUSINESS

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

Our operating subsidiary, ImmuneRegen BioSciences, Inc., was founded in October 2002. As a result, we are a development stage company with a limited operating history that makes it impossible to reliably predict future growth and operating results. Our business and prospects must be considered in light of the risks and uncertainties frequently encountered by companies in their early

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

stages of development. In particular, we have not demonstrated that we can:

- o ensure that any potential drug candidate would function as intended in large animal studies or human clinical applications;
- o obtain the regulatory approvals necessary to commercialize products that we may develop in the future;
- o manufacture, or arrange for third-parties to manufacture, future products in a manner that will enable us to be profitable;
- o establish many of the business functions necessary to operate, including sales, marketing, administrative and financial functions, and establish appropriate financial controls;

28

- o make, use, and sell future products without infringing upon third party intellectual property rights; or
- o respond effectively to competitive pressures.

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

IF WE DO NOT OBTAIN GOVERNMENT REGULATORY APPROVAL FOR OUR PRODUCTS, WE CANNOT SELL OUR PRODUCTS AND WE WILL NOT GENERATE REVENUES.

Our principal development efforts are currently centered on Radilex and Viprovex, which are potential drug candidates derived from Homspira. All drug candidates require U.S. Food and Drug Administration ("FDA") and foreign government approvals before they can be commercialized. These regulations change from time to time and new regulations may be adopted. Our research and development efforts for our drug candidates are at a very early stage; they have not been, and may not be, approved for commercial sale by the FDA or any other governmental regulatory agency. We may incur significant additional operating losses over the next several years as we fund development, clinical testing and other expenses while seeking regulatory approval. To date we have conducted limited pre-clinical studies of our potential drug candidates using various small animal models; significant additional trials are required, and we may not be able to demonstrate that these drug candidates are safe or effective. If we are unable to demonstrate the safety and effectiveness of a particular drug candidate to the satisfaction of regulatory authorities, the drug candidate will not obtain required government approval. If we do not receive FDA or foreign approvals for our products, we will not be able to sell our potential products and will not generate revenues. Even if we receive regulatory approval of a potential product, such approval may impose limitations on the indicated uses for which we may market the product, which may limit our ability to generate significant revenues.

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

Our current potential drug candidates, Radilex and Viprovex, are derived from Homspira. In addition, we plan to utilize Homspira in the development of any future products we market. If these current or future product candidates are found to be unsafe or ineffective due to the use of Homspira, we may have to modify or cease production of the products. As all of our applications utilize or will utilize Homspira, any findings that Homspira is unsafe or ineffective would severely harm our business operations, since all of



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

our primary revenue sources would be negatively affected by such findings.

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

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

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

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

Moreover, unacceptable toxicity or side effects could occur at any time in the course of human clinical trials or, if any products are successfully developed and approved for marketing, during commercial use of any of our proposed products. The appearance of any unacceptable toxicity or side effects

29

could interrupt, limit, delay or abort the development of any of our proposed products or, if previously approved, necessitate their withdrawal from the market.

THE MARKET FOR TREATING ASPECTS OF ACUTE RADIATION SYNDROME AND EXPOSURE TO VARIOUS CHEMICAL AND BIOLOGICAL AGENTS IS UNCERTAIN AND IF WE ARE UNABLE TO SUCCESSFULLY COMMERCIALIZE RADILEX OR VIPROVEX, WE WILL NOT RECOGNIZE A SIGNIFICANT PORTION OF OUR FUTURE REVENUES, IF ANY.

We do not believe any drug has ever been approved and commercialized for the treatment of severe acute radiation injury. In addition, the incidence of large-scale exposure to nuclear, radiological or biological agents has been low. Accordingly, even if Radilex, our current drug candidate to treat aspects of acute radiation syndrome (ARS) and Viprovex, our drug candidate to treat exposure to various biological agents, are approved by the FDA, we cannot

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

predict with any certainty the size of the markets for them, if any. The potential market for Radilex and Viprovex is largely dependent on the size of stockpiling orders, if any, procured by the U.S. and foreign governments. While a number of governments have historically stockpiled drugs to treat indications such as smallpox, anthrax exposure, plague, tularemia and certain long-term effects of radiation exposure, we are unaware of any significant stockpiling orders for drugs to treat ARS.

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

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

THE LENGTHY PRODUCT APPROVAL PROCESS AND UNCERTAINTY OF GOVERNMENT REGULATORY REQUIREMENTS MAY DELAY OR PREVENT US FROM COMMERCIALIZING PROPOSED PRODUCTS, AND THEREFORE ADVERSELY AFFECT THE TIMING AND LEVEL OF FUTURE REVENUES, IF ANY.

The process of obtaining FDA and other regulatory approvals is time consuming, expensive and difficult to design and implement. Our current drug candidates, Radilex and Viprovex, will have to undergo clinical trials and the marketing and manufacturing of these drug candidates, if any, will be subject to rigorous testing procedures. Our research and development efforts are at a very early stage and Radilex and Viprovex have only undergone pre-clinical testing in mice. We may not be able to obtain the necessary approvals for clinical trials, manufacturing or marketing of Radilex and Viprovex or any other potential products, if any, derived from Homspera. Moreover, any significant delays in clinical trials will impede our ability to commercialize our applications and generate revenue and could significantly increase our development costs. The commencement and completion of clinical trials for Radilex, Viprovex or any other potential products, if any, derived from Homspera, could be delayed or prevented by a variety of factors, including:

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

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

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

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

- o testing and surveillance to monitor our future products and their continued compliance with regulatory requirements;
- o submitting products for inspection and, if any inspection reveals that the product is not in compliance, prohibiting the sale of all products;
- o suspending manufacturing; or,
- o withdrawing marketing clearance.

Additionally, the FDA's policies may change and additional government regulations may be enacted which could prevent or delay regulatory approval of

30

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.

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

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

IF WE FAIL TO OBTAIN APPROVAL FROM FOREIGN REGULATORY AUTHORITIES, WE WILL NOT BE ALLOWED TO MARKET OR SELL OUR POTENTIAL PRODUCTS IN OTHER COUNTRIES, WHICH WOULD ADVERSELY AFFECT OUR LEVELS OF FUTURE REVENUES, IF ANY.

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

Approval procedures vary among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Foreign regulatory approval processes include all of the risks associated with obtaining FDA approval set forth above, and approval by

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

the FDA does not ensure approval by the health authorities of any other country.

CLINICAL TRIALS MAY FAIL TO DEMONSTRATE THE SAFETY AND EFFICACY OF OUR POTENTIAL DRUG CANDIDATES, THE EFFECT OF WHICH COULD PREVENT OR SIGNIFICANTLY DELAY REGULATORY APPROVAL AND THEREFORE ADVERSELY AFFECT THE TIMING AND LEVEL OF FUTURE REVENUES, IF ANY.

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

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

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

31

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

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

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

- o delays in enrolling volunteers;
- o interruptions in the manufacturing of our drug candidates or other delays in the delivery of materials required for the conduct of our studies;

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

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

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

The manufacture of our product candidates or any future products, whether done by outside contractors as planned or internally, must comply with current Good Manufacturing Practices, or cGMP, regulations enforced by the FDA and foreign equivalents. If a manufacturer of our drug candidates does not conform to the cGMP regulations and cannot be brought up to such a standard, we will be required to find alternative manufacturers that do conform. This may be a long and difficult process, and may delay our ability to receive FDA or foreign regulatory approval of our products.

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

OUR LACK OF COMMERCIAL MANUFACTURING, SALES, DISTRIBUTION AND MARKETING EXPERIENCE MAY PREVENT US FROM SUCCESSFULLY COMMERCIALIZING PRODUCTS, WHICH WOULD ADVERSELY AFFECT OUR LEVEL OF FUTURE REVENUES, IF ANY.

The manufacturing process of Radilex, Viprovex or any other potential products, if any, derived from Homspira is expected to involve a number of steps and requires compliance with stringent quality control specifications imposed by us and by the FDA. We have no experience in the sales, marketing and distribution of pharmaceutical or biotechnology products and we have not manufactured any of the limited quantities of Radilex and Viprovex used in our studies to date. We may not successfully arrange for contract manufacturing of Radilex, Viprovex or any other potential products, if any, derived from Homspira in production quantities and this could prevent us from commercializing products or limit our profitability from any such proposed products.

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

We may enter into arrangements with contract manufacturing companies in order to meet requirements for Radilex, Viprovex and Homspira 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, if any. Further, contract manufacturers must also operate in compliance with the cGMP requirements; failure to do so could result in, among other things, the disruption of our proposed product supplies. Our planned dependence upon third parties for the manufacture of our proposed products may adversely affect our profit margins and our ability to develop and deliver proposed products on a

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

timely and competitive basis.

32

For the manufacture of Radilex, Viprovex and Homspera, we obtain synthetic peptides from third party manufacturers. If any of these proposed manufacturing operations prove inadequate, there may be no assurance that any other arrangements may be established on a timely basis or that we could establish other manufacturing capacity on a timely basis. Although, we believe that the synthetic substance P and other materials necessary to produce Radilex, Viprovex and Homspera are readily available from various sources, and several suppliers are capable of supplying Homspera 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 RADILEX, VIPROVEX AND HOMSPERA WHICH WOULD ADVERSELY AFFECT OUR LEVEL OF FUTURE REVENUES, IF ANY.

Our ability to earn any revenue on Radilex, Viprovex or any other potential products, if any, derived from Homspera will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health coverage insurers, managed care organizations and other organizations. Failure to obtain appropriate reimbursement may prevent us from successfully commercializing Radilex, Viprovex or any other potential products, if any, derived from Homspera. Third-party payers are increasingly challenging the prices of medical products and services. If purchasers or users of Radilex, Viprovex or any such other potential products, if any, derived from Homspera are not able to obtain adequate reimbursement for the cost of using such products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved health care products and whether adequate third party coverage will be available.

THE MEDICAL COMMUNITY MAY NOT ACCEPT AND UTILIZE RADILEX, VIPROVEX OR ANY OTHER POTENTIAL PRODUCT, IF ANY, DERIVED FROM HOMSPERA, THE EFFECT OF WHICH WOULD PREVENT US FROM SUCCESSFULLY COMMERCIALIZING ANY PROPOSED PRODUCT AND ADVERSELY AFFECT OUR LEVEL OF FUTURE REVENUE, IF ANY.

Our ability to market and commercialize Radilex, Viprovex or any other potential product, if any, derived from Homspera depends on the acceptance of potential drug candidates based on Homspera by the medical community. We will need to develop commercialization initiatives designed to increase awareness about us and Homspera among targeted audiences, including public health activists and community-based outreach groups in addition to the investment community. Currently, we have not developed any such initiatives. Without such acceptance of potential drug candidates based on Homspera, we may not be able to successfully commercialize any proposed products or generate revenue.

PRODUCT LIABILITY EXPOSURE MAY EXPOSE US TO SIGNIFICANT LIABILITY OR COSTS WHICH WOULD ADVERSELY IMPART OUR FUTURE OPERATING RESULTS AND DIVERT FUNDS FROM THE OPERATION OF OUR BUSINESS.

We face an inherent business risk of exposure to product liability and other claims and lawsuits in the event that the development or use of our technology or prospective products is alleged to have resulted in adverse

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

effects. We may not be able to avoid significant liability exposure. We may not have sufficient insurance coverage, and we may not be able to obtain sufficient coverage at a reasonable cost. An inability to obtain product liability insurance at acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of our products. A product liability claim could hurt our financial performance. Even if we avoid liability exposure, significant costs could be incurred that could hurt our financial performance.

WE MAY FAIL TO PROTECT ADEQUATELY OUR PROPRIETARY TECHNOLOGY, WHICH WOULD ALLOW COMPETITORS TO TAKE ADVANTAGE OF OUR RESEARCH AND DEVELOPMENT EFFORTS, THE EFFECT OF WHICH COULD ADVERSELY AFFECT ANY COMPETITIVE ADVANTAGE WE MAY HAVE.

We own two issued U.S. and two issued foreign patents and two pending Patent Cooperation Treaty (PCT) applications, seven pending U.S. provisional patent applications and 16 pending foreign provisional patent applications. Our success will depend in part on our ability to obtain additional United States and foreign patent protection for our drug candidates and processes, preserve our trade secrets and operate without infringing the proprietary rights of third parties. We place considerable importance on obtaining patent protection for significant new technologies, products and processes.

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

33

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.

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

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, WHICH WOULD ADVERSELY AFFECT OUR LEVEL OF FUTURE REVENUES, IF ANY.

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

In addition, whether or not our applications are issued, or issued with limited coverage, others may receive patents that contain claims applicable to our potential products. Patents we are not aware of may adversely affect our ability to develop and commercialize any potential products.

The patent positions of biotechnology and pharmaceutical companies are often highly uncertain and involve complex legal and factual questions. Therefore, the breadth of claims allowed in biotechnology and pharmaceutical patents cannot be predicted. We also rely upon non-patented trade secrets and know how, and others may independently develop substantially equivalent trade secrets or know how. We also rely on protecting our proprietary technology in part through confidentiality agreements with our current and former corporate collaborators, employees, consultants and certain contractors. These agreements may be breached, and we may not have adequate remedies for any such breaches. Litigation may be necessary to defend against claims of infringement, to enforce our patents or to protect trade secrets. Litigation could result in substantial costs and diversion of management efforts regardless of the results of the litigation. An adverse result in litigation could subject us to significant liabilities to third parties, require disputed rights to be licensed or require us to cease using certain technologies.

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

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



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

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

FAILURE TO COMPLY WITH ENVIRONMENTAL LAWS OR REGULATIONS COULD EXPOSE US TO SIGNIFICANT LIABILITY OR COSTS WHICH WOULD ADVERSELY IMPACT OUR OPERATING RESULTS AND DIVERT FUNDS FROM THE OPERATION OF OUR BUSINESS HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS.

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

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

The execution of our present business plan depends on the continued services of Michael K. Wilhelm, our Chief Executive Officer and President. We currently maintain a key-man insurance policy for \$1,000,000, payable to the company, on his life. While we have entered into employment agreements with Mr. Wilhelm, the loss of any of his services would be detrimental to us and could have a material adverse effect on our business, financial condition and results of operations.

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 ownership discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would be beneficial to other stockholders.

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

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

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 OTCBB to securities of issuers that are current in their reports filed with the Securities and Exchange Commission. The effect on the OTCBB 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.

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

35

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. An aggregate of 58,194,009 shares of our common stock are being registered with the SEC in a Form SB-2 registration statement. The registration and subsequent sales of such shares of common stock will likely have an adverse effect on the market price of our common stock.

The registration and subsequent sales of shares of our common stock will likely have an adverse effect on the market price of our common stock. From time to time, certain stockholders of our company may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Act ("Rule 144"), subject to certain limitations. In general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who has satisfied a one-year holding period 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

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

for, equity securities and upon the exercise of options and warrants, security holders may experience additional dilution.

The 366,420 shares of our common stock, and 450,000 shares of our common stock issuable upon warrants presently issued and outstanding as of the date hereof are held by promoters of our prior company, GPN Networks, Inc., or such promoters' affiliates and assignees, or their transferees. It should be noted that because GPN Network, Inc. was a "blank check" company as that term is defined under the Securities Act, these shares may not be sold by these promoters or their affiliates and assignees, or their transferees, pursuant to Rule 144 of the Securities Act. The position of the staff of the Division of Corporation Finance of the Securities and Exchanges Commission is that any such resale transaction under Rule 144 would appear to be designed to distribute or redistribute such shares to the public without coming within the registration requirements of the Securities Act. Therefore, these promoters or their affiliates and assignees, or their transferees, can only resell the shares they hold as of the date hereof through a registration statement filed under the Securities Act. All of these shares are being registered hereunder.

THERE IS NO CAP ON THE SHARES AND WARRANTS WE MAY ISSUE PURSUANT TO THE DELAYED REGISTRATION PENALTY PROVISION UNDER THE OCTOBER 2004 PRIVATE PLACEMENT, WHICH MAY ADVERSELY AFFECT THE MARKET PRICE OF OUR STOCK.

Under the October 2004 private placement, we agreed to register the shares sold in the transaction, along with the shares underlying the warrants sold within ninety days from the closing date of the private placement. If these securities were not so registered, we would incur a penalty equivalent to an additional 2% of the shares and warrants to be registered for every 30 days that we failed to complete the registration. Through March 20, 2006, we have accrued 6,456,800 shares and 2,542,400 warrants pursuant to this penalty provision. No cap exists to limit the penalty for failure to register the shares and warrants in the October 2004 private placement. Accordingly, the amount of additional equity securities we issue pursuant to the delayed registration penalty may adversely affect the market price of our common stock and the rights of our stockholders may be substantially reduced. Moreover, as of the date of this report, our authorized capital consists of 100,000,000 shares of common stock. As of March 20, 2006, we have fully diluted 90,633,160 shares of common stock outstanding. Therefore, because no cap exists to limit the issuance of penalty shares, we may not have a sufficient number of authorized shares available for the settlement of the registration penalty. As a result, the investors entitled to these shares may take legal or other action against us, which may cause us to pay substantial damages and adversely affect our business.

OUR COMMON STOCK IS CONSIDERED A "PENNY STOCK," AND IS SUBJECT TO ADDITIONAL SALE AND TRADING REGULATIONS THAT MAY MAKE IT MOVE DIFFICULT TO SELL.

Our common stock is considered to be a "penny stock" since it does not qualify for one of the exemptions from the definition of "penny stock" under Section 3a51-1 of the Securities Exchange Act for 1934 as amended (the "Exchange Act"). Our common stock is a "penny stock" because it meets one or more of the

following conditions (i) the stock trades at a price less than \$5.00 per share; (ii) it is NOT traded on a "recognized" national exchange; (iii) it is NOT quoted on the Nasdaq Stock Market, or even if so, has a price less than \$5.00 per share; or (iv) is issued by a company that has been in business less than three years with net tangible assets less than \$5 million.

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

The principal result or effect of being designated a "penny stock" is that securities broker-dealers participating in sales of our common stock will be subject to the "penny stock" regulations set forth in Rules 15c-2 through 15c-9 promulgated under the Exchange Act. For example, Rule 15c-2 requires broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document at least two business days before effecting any transaction in a penny stock for the investor's account. Moreover, Rule 15c-9 requires broker-dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any penny stock to that investor. This procedure requires the broker-dealer to (i) obtain from the investor information concerning his or her financial situation, investment experience and investment objectives; (ii) reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has sufficient knowledge and experience as to be reasonably capable of evaluating the risks of penny stock transactions; (iii) provide the investor with a written statement setting forth the basis on which the broker-dealer made the determination in (ii) above; and (iv) receive a signed and dated copy of such statement from the investor, confirming that it accurately reflects the investor's financial situation, investment experience and investment objectives. Compliance with these requirements may make it more difficult and time consuming for holders of our common stock to resell their shares to third parties or to otherwise dispose of them in the market or otherwise.

### ITEM 2. DESCRIPTION OF PROPERTY

Our corporate headquarters are currently located at 4021 N. 75th Street, Suite 201, Scottsdale, Arizona 85251, where we have leased approximately 1,800 square feet of office space through September 30, 2007. Our rent expense is \$2,320 per month in year one and will increase to \$2,380 in year two. We believe that our facilities are adequate for our current needs and suitable additional or substitute space will be available in the future to replace our existing facilities, if necessary, or accommodate expansion of our operations.

### 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.

The judgment was subsequently settled in full for a cash payment of \$35,107 paid on August 2, 2005 releasing us from all obligations under the judgment.

### 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 2005.

## PART II

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

Our common stock is approved for quotation on the NASD OTC Bulletin Board under the symbol "IRBO". The following table sets forth the high and low bid prices for our common stock for the periods noted, as reported by the National Daily Quotation Service and the Over-The-Counter Bulletin Board. Quotations reflect inter-dealer prices, without retail mark-up, markdown or commission and may not represent actual transactions.

	2006	
	High	Low
1st Quarter (through March 24, 2006)	\$ 0.35	\$ 0.20

  

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

  

	2004	
	High	Low
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 March 24, 2006, the closing price of our common stock as reported by the OTC Bulletin Board was \$0.31 per share. There were approximately 520 shareholders of record and beneficial stockholders of our common stock as of March 10, 2006. We have not paid any dividends on our common stock since inception and do not intend to do so in the foreseeable future.

## UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

During the three months ended December 31, 2005, the Company issued warrants to purchase 62,467 shares of common stock at prices ranging from \$0.125 to \$1.00 per share. Pursuant to the terms of their respective agreement with us, these warrants were granted to current members of the Bioterrorism Advisory Board, Drug Development Advisory Board and the Oncology and Dermatology Advisory Board for participation during the quarter ended December 31, 2005. The warrants will bear a restrictive legend regarding the sale or transfer of such or the underlying securities. The warrants were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder. There were less than 35 investors and each investor had such knowledge and experience in financial and business

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

matters that the investor was capable of evaluating the merits and risks of investing in the warrants. No general solicitation or advertising was undertaken in connection with the offer and sale of these shares. Each investor was also provided with access to our Exchange Act reports including our annual report on Form 10-KSB and our quarterly reports on Form 10-QSB.

During the fiscal year ended December 31, 2005, the Company accrued the issuance of 5,242,307 shares of common stock and warrants to purchase an additional 2,064,187 shares of common stock pursuant to a penalty calculation with regard to the late registration of shares sold in a private placement in October 2004.

### 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.

38

### 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.

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

### OVERVIEW

We were originally incorporated in the State of Delaware in June 1985 under the name Vocaltech, Inc. to develop, design, manufacture and market products utilizing proprietary speech-generated tactile feedback devices. We completed our initial public offering of our securities in October 1987. In January 1992, we effected a 1-for-6.3 reverse stock split of our common stock. We changed our name to InnoTek, Inc. in November 1992. In December 1994, we acquired all of the outstanding stock of InnoVisions, Inc., a developer and marketer of skin protective products, discontinued our prior operations in their entirety and changed our name to DermaRx Corporation. In April 2000, we effected a reverse merger with a subsidiary of Go Public Network, Inc., which was engaged in assisting early-stage development and emerging growth companies with financial and business development services. We changed our name to GoPublicNow.com, Inc., effected a 1-for-5 reverse stock split and discontinued our prior operations in their entirety. In November 2000, we changed our name to GPN Network, Inc. In July 2001, we discontinued the operations of GPN Network, Inc. in their entirety and began looking for appropriate merger partners. Our objective became the acquisition of an operating company with the potential for growth in exchange for our securities. In July 2003, we effected a reverse merger with ImmuneRegen BioSciences, Inc., adopted our current business model and thereafter changed our name to IR BioSciences Holdings, Inc. In July 2003, we effected a 1-for-20 reverse stock split, and in April 2004, we effected a 2-for-1 stock split. 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 potential therapeutics for a number of applications. All potential therapeutics in development are based on Sar9, Met (O2)11-Substance P, an analog of the naturally occurring human neuropeptide Substance P. This neuropeptide can be found throughout the body, including in the airways of humans and many other species. We use the generic name Homspera to refer to the synthetic Sar9, Met (O2)11-Substance P peptide. All of our research and development efforts are early, pre-clinical stage and Homspera has only undergone exploratory studies to evaluate its biological activity in small animals.

Currently, the majority of our development efforts are centered on two potential therapeutic applications for the active ingredient in Homspera. Radilex is being formulated specifically for the treatment of acute exposure to radiation. Viprovex is being formulated specifically for applications relating to the treatment of maladies caused by exposure to various chemical and

39

biological agents. We are currently sponsoring ongoing pre-clinical studies in these areas, specifically two mouse radiation studies on the efficacy of Radilex in treating acute radiation exposure and a study on the efficacy of Viprovex in treating exposure to anthrax. In addition, we have designed the protocols for additional radiation studies in mice using Radilex and an avian flu study in mice using Viprovex. Both studies have institutions with facilities committed to perform them when, and if, protocols and funding are finalized.

To date we have submitted preliminary study data to the U.S. Food and Drug Administration (FDA) and have been issued two Pre-Investigational New Drug (PIND) numbers, one for use of Homspera (now Radilex) in the treatment of acute

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

radiation syndrome and the other for use of Viprovex in the treatment of avian influenza. In addition, we have recently submitted a PIND data package for the use of Viprovex in the treatment of chemical exposure. We intend to file final radiation study data from mice with the FDA within six months, and at that time we plan to request a meeting with the FDA regarding the authorization of a large animal study protocol to test the efficacy of Radilex as a treatment for acute radiation syndrome. Also within the next six months, we plan to submit an Investigational New Drug (IND) application for the use of Viprovex in treating Acute Respiratory Distress Syndrome (ARDS)

We have filed patent applications and provisional patent applications, where applicable, in many jurisdictions, inside and outside of the United States, for the use of the active ingredient Sar9, Met (O2)11-Substance P in applications that we are researching. We own two issued U.S. and two issued foreign patents and two pending Patent Cooperation Treaty (PCT) applications, seven pending U.S. provisional patent applications and 16 pending foreign provisional patent applications.

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

The results of our preclinical studies and clinical trials may not be indicative of 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 commercial applications using Homspera or any derivatives thereof. Delays in planned patient enrollment in our clinical trials may result in increased costs, program delays or both. None of our potential applications may prove to be safe or effective in clinical trials. Approval of the FDA or other regulatory approvals, including export license permissions, may not be obtained and even if successfully developed and approved, our potential applications may not achieve market acceptance. Any applications resulting from our programs may not be successfully developed or commercially available for a number of years, if at all.

As traditional efficacy studies would require healthy human volunteers to be exposed to the potentially lethal agents or pathogens, this cannot be done. Therefore, we may apply for approval based upon a new rule adopted by the FDA in 2002, titled "Approval of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible" (Code of Federal Regulations, Title 21, Part 314, Subpart I), which is also referred to as the "animal efficacy rule." Pursuant to this new rule, in situations where it would be unethical to conduct traditional Phase II and Phase III efficacy studies in humans, as is the case with our applications relating to the treatment of maladies caused by exposure to high level gamma radiation and various chemical and biological agents, the FDA will review new drugs for approval on the basis of safety in humans and efficacy in relevant animal models. Through development under this paradigm, management believes near-term development opportunities may exist and development costs are lessened compared to the more traditional drug development model, as Phase II and Phase III of the FDA required drug approval process are not required. Under either scenario, we will not have marketable applications unless and until our drug candidates complete all required safety studies and clinical trials and receive FDA approval in the United States or approval by regulatory agencies outside of the United States.

Prior to FDA approval, Radilex and Viprovex may become eligible for



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

purchase by the U.S. government. Project BioShield legislation contains provisions enabling the U.S. Department of Health and Human Services, or 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 our studies, in the opinion of management, indicate that Radilex may have efficacy in the treatment of the life-threatening effects of radiation exposure and Viprovex to exposure to various biological and chemical agents, we believe there may be interest by government agencies to stockpile Radilex and/or Viprovex if it is successfully developed. However, there is no assurance that any of such orders will be forthcoming and we have received no indication from Project BioShield or any other agency that it intends to purchase any quantities of Radilex or Viprovex.

40

To date, we have not obtained regulatory approval for or commercialized any applications using Homspera or any of its derivatives. We have incurred significant losses since our inception and we expect to incur annual losses for at least the next 3 years as we continue with our drug discovery and development efforts.

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

### PLAN OF OPERATIONS

We expect to continue to incur increasing operating losses for the foreseeable future, primarily due to our continued research and development activities attributable to Radilex, Viprovex or any other proposed product, if any, derived from Homspera and general and administrative activities.

Due to our liquidity and limited cash available our spending on research and development activities in 2004 and 2005 was limited. We spent approximately \$113,731 and \$150,091 in 2005 and 2004, respectively, in research and development activities related to the development of Radilex and Viprovex as potential protectants against the effects of chemical, biological, radiological and nuclear threats. From our inception in October 2002, we have spent \$306,794 in research and development activities. These costs only include the manufacture and delivery of our drug by third party manufacturers and payments to Contract Research Organizations for consulting related to our studies and costs of performing such studies. Significant costs relating to research and development, such as consulting fees for Drs. Witten and Seigel, among others, have been classified in consulting fees for consistency of financial reporting.

We anticipate that during the next 12 months we will increase our research and development spending to a total of approximately \$3,500,000 in an effort to further develop Radilex and Viprovex. 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, and therefore adversely affect the timing and level of future revenues, if any."

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

### PRODUCT RESEARCH AND DEVELOPMENT

We incurred an expense of \$113,731 for the year ended December 31, 2005 in research and development activities related to the development of Radilex and Viprovex versus an expense of \$150,091 for the year ended December 31, 2004. Due to our liquidity and limited cash available, our spending on research and development activities was limited. From our inception in October 2002, we have spent \$306,794 in research and development activities. These costs only include the manufacture and delivery of our drug by third party manufacturers and payments to Contract Research Organizations for consulting related to our studies and costs of performing such studies. Significant costs relating to research and development, such as consulting fees for Drs. Witten and Seigel, among others, have been classified in consulting fees for consistency of financial reporting.

If we are successful in obtaining additional funding through grants or investment capital, we anticipate that during the next 12 months we will increase our research and development spending to a total of approximately \$3,500,000 in an effort to further develop Radilex, as a medical countermeasure against radiological threats, and Viprovex, as a protectant against threats from various biological agents. The research and development cost includes a radiation study on large animals, which we estimate will cost up to \$2,500,000 depending on the choice of contractor, additional animal pharmacology studies, formulation and animal safety/toxicity studies, as well as, small pilot pharmacological studies exploring possible additional indications. If we are unable to raise additional capital, our research and development activities may be lessened. The drug development, clinical trial and regulatory process is lengthy, expensive and uncertain and subject to numerous risks.

We intend to apply to the FDA for approval for the use of Radilex for the treatment of acute radiation syndrome and for approval for the use of Viprovex for the treatment of maladies caused by chemical and biological exposure based upon the "animal efficacy rule." We believe near-term development opportunities may exist and development costs could potentially be lessened compared to the more traditional drug development model, as Phase II and Phase III of the FDA required drug approval process are not required. Even if we are able to develop this potential application under the animal efficacy rule, we will not have marketable applications unless and until our drug candidates complete all required safety studies and clinical trials and receive FDA

41

approval in the United States or approval by regulatory agencies outside of the United States. If we are successful in completing the study and achieve the desired results, we intend to submit the necessary documentation to the FDA and other regulatory agencies for approval. If approval for Radilex and/or Viprovex is granted, we expect to begin efforts to commercialize our product, if any, immediately thereafter. If approved, we are anticipating revenues from the sale of Radilex and Viprovex, if any, beginning in calendar year 2009.

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, 2005, we had no revenues from any product sales, royalties or licensing fees, and have not achieved profitability on a quarterly or annual basis. Our ability to achieve profitability depends upon, among other things, our ability to develop products, obtain regulatory approval for products under development and enter into agreements for product development, manufacturing and commercialization. Moreover, we may never achieve significant revenues or profitable operations from the sale of any of our potential products or

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

technologies.

Our major research and development projects include:

Research and Development of Radilex in Radiological Exposure Applications.

-----

We have commenced initial testing of Radilex to record its potential therapeutic effects on the treatment of toxic radiation exposure. Our current and past studies are based on initial studies conducted by our co-founders, Drs. Mark Witten and David Harris. Subsequently, we have sponsored and/or co-sponsored six radiation studies on rodents. In addition, we are currently sponsoring two ongoing radiation studies, one at the University of Arizona and one at Oak Ridge National Laboratory.

We prepared the protocols for what we believe will be our final phase of rodent studies for a radiation sensitivity study on rodents to be conducted at the Oak Ridge National Laboratory in which we will attempt to further validate our prior studies. This study commenced on February 28, 2006. We estimate that the study will be completed within 3 months at an estimated cost of \$90,000. 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 potential treatment to acute radiation sickness. We expect this study to begin within the next 12 to 18 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 expect up to an additional \$2,500,000 will be required to complete this study. We estimate the completion of this study will be in 18 to 24 months.

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

Research and Development of Viprovox in Chemical and Biological Exposure Applications.

-----

We are sponsoring a series of studies with Hyperion Biotechnology Inc. at their laboratory facilities located at Brooks City-Base in San Antonio, Texas with the cooperation of the U.S. Air Force School of Aerospace Medicine (USAFSAM). The first of these studies was initiated in October 2005. Logistical considerations related to number of animals requiring exposure and performance of a full Viprovox dose-response curve within specified time limits following anthrax exposure required the experiment be performed in two sections, and it is incomplete at this time. The second half of the full dose-ranging experiment began in February, 2006. We estimate that the study will be completed within 3 months at an estimated cost of \$51,450. If we are successful in achieving desirable results against anthrax, we intend to design the protocols and begin further studies for this and other 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 anthrax 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.

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

### OFF-BALANCE SHEET ARRANGEMENTS

There were no off-balance sheet arrangements made in 2005.

### REVENUES

We have not generated any revenues from operations from our inception. We believe we will begin earning revenues from operations during calendar year 2009 as we transition from a development stage company.

42

### COSTS AND EXPENSES

From our inception through December 31, 2005, we have incurred losses of \$11,799,134. These expenses were associated principally with equity-based compensation to employees and consultants, product development costs and professional services.

### NET LOSS

-----

For the reasons stated above, our net loss for the twelve months ending December 31, 2005 was \$4,591,107, or \$0.07 per share. For the period of inception (October 30, 2002) through December 31, 2005, our net loss was \$11,799,134, or \$0.30 per share. We expect that losses will continue through the period ending December 31, 2009.

Our independent certified public accountants have stated in their report included in this Form 10-KSB that we have incurred a net loss and negative cash flows from operations of \$4,591,107 and \$1,884,113, respectively, for the year ended December 31, 2005. This loss, in addition to a lack of operational history, raises substantial doubt about our ability to continue as a going concern. In the absence of significant revenue and profits, and since we do not expect to generate significant revenues in the foreseeable future, we, in order to fund operations, will be completely dependent on additional debt and equity financing arrangements. There is no assurance that any financing will be sufficient to fund our capital expenditures, working capital and other cash requirements for the fiscal year ending December 31, 2006. No assurance can be given that any such additional funding will be available or that, if available, can be obtained on terms favorable to us. If we are unable to raise needed funds on acceptable terms, we will not be able to develop or enhance our products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, we will not be able to continue operations.

### Penalties for Late Registration

-----

During the fiscal year December 31, 2005, we accrued the issuance of 5,242,307 shares of common stock and warrants to purchase an additional 2,064,187 shares of common stock pursuant to a penalty calculation with regard to the late registration of shares sold in a private placement in October 2004.

In October 2004, we completed a private placement sale of shares of our common stock and warrants to purchase additional shares of common stock. We issued in the private placement an aggregate of 19,600,000 shares of our common

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

stock and warrants to purchase 9,800,000 shares of our common stock. We agreed to register these shares along with the shares underlying these warrants within ninety days from the closing date of the transaction, or we would incur a penalty equivalent to an additional 2% of the shares and warrants to be registered for every 30 days that we fail to complete this registration. This penalty amounts to an aggregate of 461,200 shares and 181,600 warrants per 30 day period until such a time as this registration statement is made effective. As of December 31, 2005, we are required to issue an additional 5,242,307 shares of common stock and warrants to purchase an additional 2,064,187 shares of common stock. At the time these liabilities were incurred, the shares were valued at \$1,991,923 and the warrants were valued at \$638,838. The shares were valued at the market price of the Company's common stock at the time the liabilities were incurred. The warrants were valued utilizing the Black-Scholes valuation model. The aggregate amount of \$2,630,761 was charged to operations as cost of Penalty for late registration of shares during the year ended December 31, 2005. The shares and warrants were re-valued at December 31, 2005, and the result of this re-valuation was to decrease the value of the shares by \$314,385 and to decrease the value of the warrants by \$254,693. These decreases were credited to other (income) expense during the year ended December 31, 2005. At December 31, 2005, the fair value of the common stock issuable under the penalty for late registration of shares is \$1,677,538, and the fair value of the warrants issuable under the penalty for late registration of shares is \$384,145. These amounts appear as current liabilities on the Company's condensed consolidated balance sheet at December 31, 2005.

We anticipate completing the registration of these shares during the quarter ended June 30, 2006, but expect that an obligation to issue approximately 2,136,893 additional shares and 841,413 additional warrants at an aggregate cost of approximately \$840,000 will be incurred. There is no guarantee that we will be able to complete the registration within the anticipated timeframe.

### LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2005, we had current assets of \$290,367 consisting of cash of \$265,860 and prepaid services of \$24,507. Also, at December 31, 2005, we had current liabilities of \$2,563,811, consisting of accounts payable and accrued liabilities of \$2,563,811. This resulted in a working capital deficit of \$2,273,444. During the twelve months ended December 31, 2005, we used cash in

43

operating activities of \$1,884,113. From the date of inception (October 30, 2002) to December 31, 2005, we had a net loss of \$11,799,134 and used cash of \$3,958,458 in operating activities. We met our cash requirements from our inception through December 31, 2005 via the private placement of \$3,263,902 of our common stock and \$968,503 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 19,600,000 shares of our common stock and warrants to purchase 9,800,000 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.

We currently have no revenue. There is no guarantee that our business model will be successful, or that we will be able to generate sufficient revenue to fund future operations. As a result, we expect our operations to continue to

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

use net cash, and that we will be required to seek additional debt or equity financings during the coming quarters. Since inception, we have financed our operations through debt and equity financing. While we have raised capital to meet our working capital and financing needs in the past, additional financing is required in order to meet our current and projected cash flow deficits from operations and development of our product line. We met our cash requirements from our inception through December 31, 2005 via the private placement of \$3,263,902 net of costs of our common stock, \$1,194,856 of this was from the exercise of common stock purchase warrants net of costs. An additional \$968,503 was received from the issuance of notes payable, net of repayments.

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 \$1,190,856 from the tender offer, net of costs.

During the year ended December 31, 2005, we repaid two notes payable, \$14,997 in cash and \$65,003 by converting into 232,153 shares of common stocks at \$0.28 per share pursuant to the terms of the promissory note dated September 26, 2001. The first note which accrued interest at 8% was repaid in full for \$4,998 (\$3,900 principal & \$1,097 accrued interest) on April 11, 2005, releasing us from further obligations under the note. On June 7, 2005, the remaining note in the principal amount of \$50,000 and all accrued interest of \$15,003 were converted into 232,153 shares of our common stock in accordance with the original terms of the note.

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 note holder. Consideration of \$100.00 was paid by us to the note holder. Under the terms of the agreement, the note holder released us from all claims, known or unknown, relating to the amount owed.

On June 13, 2005, we issued 80,000 shares of common stock for cash of \$4,000 pursuant to the exercise of a warrant at \$0.05 per share.

Between June 2003 and August 2004 eleven investors entered into fifteen convertible promissory notes totaling \$558,500 with interest rates ranging between 8% and 12% and having various maturities. In October 2004, these notes were converted into equity in the aggregate amount of \$558,500 plus accrued interest of \$56,757. For full and complete satisfaction of debt, we issued to the note holders the following: (a) a number of shares of our common stock determined by dividing the debt amount by an amount between \$0.075 and \$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 debt conversion we issued an aggregate of 6,694,149 shares of common stock and warrants to purchase 3,347,076 shares of common stock. Under the terms of the conversion agreement, the note holders released us from all claims, known or unknown, relating to the debt amount.

Pursuant to our employment agreement with Michael Wilhelm, our President and Chief Executive Officer, dated December 16, 2002, we paid a salary of \$125,000 and \$175,000 to Mr. Wilhelm during the first and second years of his employment, respectively. Thereafter we paid through August 10, 2005, an annual salary of \$250,000. On August 10, 2005, we entered into a new employment agreement with Mr. Wilhelm. The new employment agreement calls for a salary at the rate of \$275,000 per annum and provides for bonus incentives. Mr. Wilhelm's

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

salary is payable in regular installments in accordance with the customary payroll practices of our company.

44

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.

On December 16, 2002 we entered into a consulting agreement on a month-to-month basis with Dr. Mark Witten, our Director. Under the terms of this agreement, Dr. Witten agrees to place at the disposal of us his judgment and expertise in the area of acute lung injury. In consideration for these services, we agreed to pay Dr. Witten a non-refundable fee of \$5,000 per month. In January 2006, the company received correspondence from Dr. Witten stating that he would terminate his consulting contract if his specific requirements were not met. We subsequently accepted his termination effective February 1, 2006.

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 September 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 \$3,162,702). Based on our current plan of operations all of our current funding is expected to be depleted by the end of March 2006. If we are not successful in generating sufficient liquidity from operations or in raising sufficient capital resources, it would have a material adverse effect on our business, results of operations, liquidity and financial condition.

While we have 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 potential products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets or seeking an acquisition partner.

Until such time, if at all, as we receive adequate funding, we intend to continue to defer payment of all of our obligations which are capable of being deferred, which actions have resulted in some vendors demanding cash payment for their goods and services in advance, and other vendors refusing to continue to do business with us. 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. Based on our operating expenses and anticipated research and development activities, we believe that we will require an additional \$5 million to meet our expenses over the next 12 months.

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

### Acquisition or Disposition of Plant and Equipment

-----

We did not dispose or acquire any significant property, plant or equipment for the year ended December 31, 2005. 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, 2005, we have relied on the services of outside consultants for services and currently have five total employees, two contract employees and three full-time employees. Our full-time employees are Michael K. Wilhelm, our Chief Executive Officer; John Fermanis, our Chief Financial Officer; and, the third serves in an administrative role. In order for us to attract and retain quality personnel, we anticipate we will have to offer competitive salaries to future employees. We do not anticipate our employment base will significantly change during the next twelve months, 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.

45

### CRITICAL ACCOUNTING POLICY

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

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

#### Stock-based Compensation

-----

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



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

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 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.

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

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.

47

### ITEM 7. FINANCIAL STATEMENTS

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FINANCIAL STATEMENTS AND SCHEDULES

DECEMBER 31, 2005 AND 2004

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

IR BIOSCIENCES HOLDINGS, INC.

F-1

Edgar Filing: IR BIOSCIENCES HOLDINGS INC - Form 10KSB

IR Biosciences Holdings, Inc.

Index to Financial Statements

Page No.

-----

Report of Independent Registered Certified Public Accounting Firm.....F-3

Consolidated Balance Sheet at December 31, 2005.....F-4

Consolidated Statements of Losses for the two years ended  
December 31, 2005 and 2004 and the period October 30, 2002  
(Date of Inception) through December 31, 2005.....F-5

Consolidated Statements of Stockholders' Equity (Deficit) for the period  
October 30, 2002 (Date of Inception) through December 31, 2005.....F-6 to F-9

Consolidated Statements of Cash Flows for the two years ended  
December 31, 2005 and 2004 and the period October 30, 2002  
(Date of Inception) through December 31, 2005.....F-10 to F-11

Notes to Consolidated Financial Statements.....F-12 to F-25

F-2

RUSSELL BEDFORD STEFANOU MIRCHANDANI LLP  
CERTIFIED PUBLIC ACCOUNTANTS

REPORT OF INDEPENDENT REGISTERED CERTIFIED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of IR BioSciences Holdings, Inc. a development stage company as of December 31, 2005 and the related consolidated statements of losses, deficiency in stockholders' equity, and cash flows for the years ended December 31, 2005 and 2004 and the period October 22, 2002 (date of inception) through December 31, 2005. These financial statements are the responsibility of the company's management. Our responsibility is to express an opinion on the financial statements based upon

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

our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of IR BioSciences Holdings, Inc. a development stage company at December 31, 2005 and the results of its operations and its cash flows for the years ended December 31, 2005 and 2004, and the period October 22, 2002 (date of inception) through December 31, 2005 in conformity with accounting principles generally accepted in the United States of America.

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

/s/ RUSSELL BEDFORD STEFANOU MIRCHANDANI LLP

-----  
Russell Bedford Stefanou Mirchandani LLP

New York, New York  
March 24, 2005

F-3

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

	December 31, 2005
	-----
Assets	
Current assets	
Cash and cash equivalents	\$ 265,860
Prepaid services and other current assets	24,507
	-----
Total current assets	290,367
Deposits and other assets	2,260
Furniture and equipment, net of accumulated depreciation of \$3,862	4,226
	-----

Edgar Filing: IR BIOSCIENCES HOLDINGS INC - Form 10KSB

Total assets	\$ 296,853
	=====
Liabilities and Stockholders' Deficit	
Current liabilities	
Accounts payable and accrued liabilities	502,128
Warrant portion of penalty for late registration of shares - with registration rights (See note E)	384,145
Common stock portion of penalty for late Registration of shares (See note E)	1,677,538
	-----
Total current liabilities	2,563,811
Commitments and Contingencies	--
Stockholders' deficit	
Preferred stock, 0.001 par value: 10,000,000 shares authorized, no shares issued and outstanding	--
Common stock, \$0.001 par value; 100,000,000 shares authorized; 69,436,319 shares issued and outstanding at December 31, 2005	69,435
Additional paid-in capital	9,465,501
Deferred compensation	(2,760)
Deficit Accumulated during the Development Stage	(11,799,134)
	-----
Total stockholder's deficit	(2,266,958)
	-----
Total liabilities and stockholders' deficit	\$ 296,853
	=====

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

F-4

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

	For the Year Ended December 31, 2005	For the Year Ended December 31, 2004	For the Octobe 2002 Decembe 200
	-----	-----	-----
Operating expenses:			

Edgar Filing: IR BIOSCIENCES HOLDINGS INC - Form 10KSB

Selling, general and administrative expenses	\$ 2,534,417	\$ 4,498,390	\$ 8,12
Merger fees and costs	--	--	35
Financing cost	--	--	9
Impairment of intangible asset	6,393	--	
	-----	-----	-----
Total operating expenses	2,540,810	4,498,390	8,57
	-----	-----	-----
Operating loss	(2,540,810)	(4,498,390)	(8,57
Other expense:			
Cost of penalty for late registration of shares	2,630,761	--	2,63
Gain from marking to market - warrant portion of penalty for late registration of shares	(254,693)	--	(25
Gain from marking to market - stock portion of penalty for late registration of shares	(314,385)	--	(31
Interest (income) expense, net	(11,386)	807,017	1,16
	-----	-----	-----
Total other (income) expense	(2,050,297)	807,017	3,22
	-----	-----	-----
Loss before income taxes	(4,591,107)	(5,305,407)	(11,79
Provision for income taxes	--	--	
	-----	-----	-----
Net loss	\$ (4,591,107)	\$ (5,305,407)	\$ (11,79
	=====	=====	=====
Net loss per share - basic and diluted	\$ (0.07)	\$ (0.16)	\$
	=====	=====	=====
Weighted average shares outstanding - basic and diluted	67,691,598	33,510,168	38,93
	=====	=====	=====

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

F-5

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, 2005

Common Stock		Additional Paid-In Capital	Deferr Compensa
Shares	Amount		
-----	-----	-----	-----

Edgar Filing: IR BIOSCIENCES HOLDINGS INC - Form 10KSB

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
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
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	--		--		--
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

Edgar Filing: IR BIOSCIENCES HOLDINGS INC - Form 10KSB

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 year ended December 31, 2003	--	--	--
Balance at December 31, 2003	23,431,300	23,431	1,035,441

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

F-6

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, 2005

	Common Stock		Additional	Deferr
	Shares	Amount	Paid-In Capital	Compensa
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)
Shares 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	



Edgar Filing: IR BIOSCIENCES HOLDINGS INC - Form 10KSB

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	
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 diligence 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)
Beneficial 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	

F-7

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, 2005

Edgar Filing: IR BIOSCIENCES HOLDINGS INC - Form 10KSB

	Common Stock		Additional Paid-In Capital	Deferr Compensa
	Shares	Amount		
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 in October 2004 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 October 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, 2004	--	--	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				

Edgar Filing: IR BIOSCIENCES HOLDINGS INC - Form 10KSB

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 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 year ended December 31, 2004	--	--	--	
Balance at December 31, 2004	<u>62,423,388</u>	<u>62,423</u>	<u>7,922,943</u>	<u>(169,000)</u>

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

F-8

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, 2005

	Common Stock		Additional	Deferr
	Shares	Amount	Paid-In Capital	Compensa
	-----	-----	-----	-----
Sale of shares of common stock for cash at \$0.20 per share in Mar 2005 for warrant exercise, net of costs	6,600,778	6,600	1,184,256	
Value of warrants issued to members of advisory committees in March 2005	--	--	137,049	

Edgar Filing: IR BIOSCIENCES HOLDINGS INC - Form 10KSB

Deferred compensation in Feb 2005 to a consultant for 50,000 shares of stock at \$0.65 per share.	--	--	--	(32)
Warrants exercised at \$0.05 per share in June 2003	80,000	80	3,920	
Value of warrants issued to members of advisory committee in June 2005	--	--	70,781	
Value of warrants issued to investors and service providers in June 2005	--	--	32,991	
Issuance of 232,153 shares of common stock in July 2005 for conversion of notes payable	232,153	232	64,771	
Issuance of 100,000 shares of common stock in August 2005 to a consultant for services provided	100,000	100	9,900	
Value of warrants issued to advisory committee in September 2005 for services	--	--	20,491	
Amortization of deferred comp for the twelve months ended December, 2005	--	--	--	199
Value of warrants issued in October and December 2005 to investors and service providers	--	--	18,399	
Loss for the year ended December 31, 2005	--	--	--	
	-----	-----	-----	-----
	69,436,319	69,435	9,465,501	(2)

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

F-9

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

	For the Year Ended December 31, 2005	For the Year Ended December 31, 2004
	-----	-----
Cash flows from operating activities:		
Net loss	\$ (4,591,107)	\$ (5,305,407)
Adjustments to reconcile net loss to net cash used in operating activities:		

Edgar Filing: IR BIOSCIENCES HOLDINGS INC - Form 10KSB

Non-cash compensation	520,853	3,284,577
Cost of penalty for late registration of shares - stock portion	1,991,923	--
Cost of penalty for late registration of shares - warrant portion	638,838	--
Impairment of intangible asset	6,393	--
Interest expense	4,007	83,776
Amortization of discount on notes payable	--	704,633
Depreciation and amortization	3,201	13,255
Changes in operating assets and liabilities:		
Prepaid services and other assets	9,946	29,130
Accounts payable and accrued expenses	100,911	148,854
	-----	-----
Net cash used in operating activities	(1,884,113)	(1,041,182)
Cash flows from investing activities:		
Acquisition of property and equipment	--	(4,783)
	-----	-----
Net cash used in investing activities	--	(4,783)
Cash flows from financing activities:		
Proceeds from notes payable	--	32,500
Principal payments on notes payable and demand loans	(14,997)	--
Shares of stock sold for cash	1,190,856	1,973,045
Proceeds from exercise of warrant	4,000	--
Officer repayment of amounts paid on his behalf	--	--
Cash paid on behalf of officer	--	--
	-----	-----
Net cash provided by financing activities	1,179,859	2,005,545
Net increase (decrease) in cash and cash equivalents	(704,254)	959,580
Cash and cash equivalents at beginning of period	970,114	10,534
	-----	-----
Cash and cash equivalents at end of period	\$ 265,860	\$ 970,114
	=====	=====

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

F-10

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

For the Year Ended For the Year Ended  
December 31, 2005 December 31, 2004  
-----

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

Supplemental disclosures of cash flow information:

Cash paid during the period for:		
Interest	\$ 1,706	\$ 54
Taxes	\$ -	\$ -
Acquisition and capital restructure:		
Assets acquired	-	-
Liabilities assumed	-	-
Common stock retained	-	-
Adjustment to additional paid-in capital	-	-
Organization costs	-	-
	-----	-----
Total consideration paid	\$ -	\$ -
	=====	=====
Common stock issued in exchange for proprietary rights	\$ -	\$ -
	=====	=====
Common stock issued in exchange for services	\$ 10,000	\$ 2,878,006
	=====	=====
Common stock issued in exchange for previously incurred debt and accrued interest	\$ 65,003	\$ 695,591
	=====	=====
Common stock issued as interest	\$ -	\$ 36,000
	=====	=====
Amortization of beneficial conversion feature	\$ -	\$ 162,709
	=====	=====
Stock options and warrants issued in exchange for services rendered	\$ 279,949	\$ 406,571
	=====	=====
Debt and accrued interest forgiveness from note holders	\$ -	\$ 36,785
	=====	=====
Common stock issued in satisfaction of amounts due to an Officer and a Director	\$ -	\$ 180,000
	=====	=====
Common stock issued in satisfaction of accounts payable	\$ -	\$ 157,219
	=====	=====
Amortization of deferred compensation	\$ 199,726	\$ -
	=====	=====
Fair value of common stock and warrants in connection with the late filing of registration statement	\$ 2,630,761	\$ -
	=====	=====
Gain from marking to market - stock portion of penalty for late registration of shares	\$ 314,385	\$ -
	=====	=====
Gain from marking to market - warrant portion of penalty for late registration of shares	\$ 254,693	\$ -
	=====	=====
Impairment of intangible asset	\$ 6,393	\$ -

=====

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

F-11

IR BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY  
(A DEVELOPMENT STAGE COMPANY)  
NOTES TO FINANCIAL STATEMENTS  
FOR THE YEARS ENDED DECEMBER 31, 2005 AND 2004  
AND FOR THE PERIOD FROM OCTOBER 30, 2002  
(INCEPTION) TO DECEMBER 31, 2005

NOTE A - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

Nature of Business

-----

IR BioSciences Holdings, Inc. (the "Company," "we," or "us") formerly GPN Network, Inc. ("GPN") is currently a development stage company under the provisions of Statement of Financial Accounting Standards ("SFAS") No. 7. The Company, which was incorporated under the laws of the State of Delaware on October 30, 2002, is a biopharmaceutical company. Through our wholly owned subsidiary, ImmuneRegen BioSciences, Inc., we are engaged in the research and development of potential therapeutics for a number of applications. All therapeutics in development are based on Sar9, Met (02)11-Substance P, an analog of the naturally occurring human neuropeptide Substance P. This neuropeptide can be found throughout the body, including in the airways of humans and many other species. We use the generic name Homspera to refer to the synthetic Sar9, Met (02)11-Substance P peptide. All of our research and development efforts are early, pre-clinical stage and Homspera has only undergone exploratory studies to evaluate its biological activity in small animals.

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.

Going Concern

-----

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As shown in the accompanying financial statements during the years ended December 31, 2005 and 2004, the Company incurred losses from operations of \$ 4,591,107 and \$ 5,305,407, respectively. In addition, its current liabilities exceed its current assets by \$2,273,444 as of December 31, 2005. These factors among others may indicate that the Company will be unable to continue as a going concern for a reasonable period of time.

In order to address our capital requirements, we intend to seek to raise additional cash for working capital purposes through the public or private sales of debt or equity securities, the procurement of advances on contracts or licenses, funding from joint-venture or strategic partners, debt financing or

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

short-term loans, or a combination of the foregoing. We may also seek to satisfy indebtedness without any cash outlay through the private issuance of debt or equity securities. There can be no assurance the Company will be successful in its effort to secure additional equity financing.

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

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

F-12

### Use of Estimates

-----

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

### Cash and Cash Equivalents

-----

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

### Long-lived Assets

-----

The Company 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.



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

### 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 2005, 2004 and 2003, common stock equivalents were not considered in the calculation of the weighted average number of common shares outstanding because they would be anti-dilutive, thereby decreasing the net loss per common share.

### Liquidity

-----

As shown in the accompanying financial statements, the Company has incurred a net loss of \$11,799,134 from its inception through December 31, 2005. The Company incurred a net loss of \$ 4,591,107 and \$ 5,305,407 from operations during the years ended December 31, 2005 and 2004, respectively. The Company's has a net working capital deficit of \$2,273,444 with cash and cash equivalents of \$265,860 at December 31, 2005.

### 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 2005, 2004, and the period from October 30, 2002 (date of inception) to December 31, 2005 were \$113,731, \$150,091 and \$306,794, respectively.

F-13

### 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, 2005.

### 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

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

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 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, 2005 and 2004 and for subsequent periods.

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

	Twelve months ended December 31,	
	2005	2004
	-----	-----
Net loss, as reported	\$(4,591,107)	\$(5,305,407)
Compensation recognized under under APB 25	--	--
Compensation recognized under SFAS 123	(83,150)	--
	-----	-----
Pro forma net loss	\$(4,674,257)	\$(5,305,407)
	=====	=====
Pro forma loss per share	\$ (0.07)	\$ (0.16)
	=====	=====

### 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

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

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.

F-14

### 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, 2005 or 2004.

### 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 May 2005, the FASB issued FASB Statement No. 154, ("FAS 154"), "Accounting Changes and Error Corrections." FAS 154 establishes retrospective application as the required method for reporting a change in accounting principle in the absence of explicit transition requirements specific to the newly adopted accounting principle. FAS 154 also provides guidance for determining whether retrospective application of a change in accounting principle is impracticable and for reporting a change when retrospective application is impracticable. FAS 154 becomes effective for accounting changes and corrections of errors made in

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

fiscal years beginning after December 15, 2005. We do not expect the adoption of FAS 154 to have a material impact on our financial position, cash flows or results of operations.

In December 2004, the FASB issued FASB Statement No. 123(R), ("FAS 123(R)"), "Share-Based Payment," which is a revision of FASB Statement No. 123 ("FAS 123"), "Accounting for Stock-Based Compensation." FAS 123(R) supersedes APB Opinion No. 25, (APB 25), "Accounting for Stock Issued to Employees," and amends FASB Statement No. 95, "Statement of Cash Flows." FAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values at the date of grant and to record that cost as compensation expense over the period during which the employee is required to perform service in exchange for the award (generally over the vesting period of the award). Excess tax benefits, as defined by FAS 123(R), will be recognized as an addition to common stock. In April 2005, the SEC adopted a new rule that amends the compliance dates for FAS 123(R). In accordance with the new rule, we are required to implement FAS 123(R) at the beginning of our fiscal year that begins January 1, 2006. The Commission's new rule does not change the accounting required by FAS 123(R); it changes only the dates of compliance.

In November 2005, the FASB issued FASB Staff Position No. FAS 123(R)-3, "Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards." The alternative transition method includes simplified methods to establish the beginning balance of the additional paid-in capital pool ("APIC pool") related to the tax effects of employee share-based compensation, and to determine the subsequent impact on the APIC pool and consolidated statements of cash flows of the tax effects of employee share-based compensation awards that are outstanding upon adoption of SFAS 123(R). An entity may make a one-time election to adopt the transition method described in this guidance and may take

F-15

up to one year from the later of its initial adoption of SFAS 123(R) or the effective date of this guidance, which was November 11, 2005. We are in the process of determining whether to adopt the alternative transition method provided in FAS 123(R)-3 for calculating the tax effects of share-based compensation pursuant to SFAS 123(R).

Effective January 1, 2006, we will adopt FAS 123(R) using the modified prospective transition method, which provides for certain changes to the method for valuing share-based compensation. The valuation provisions of FAS 123(R) apply to new awards and to awards that are outstanding at the effective date and subsequently modified or cancelled. Estimated compensation expense for awards outstanding at January 1, 2006 will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under FAS 123. In accordance with the modified prospective transition method, our statements of operations for periods prior to January 1, 2006 will not be restated to reflect the impact of FAS 123(R).

Our calculation of share-based compensation expense in future periods will be calculated using the Black-Scholes option valuation model and will include the portion of share-based payment awards that is ultimately expected to vest during the period and therefore will be adjusted to reflect estimated forfeitures. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In our pro forma information required under SFAS 123 for the periods prior to 2006, we accounted for forfeitures as they occurred. For share awards granted after January 1, 2006, expenses will be amortized under the straight-line attribution method. For share awards granted prior to 2006, expenses are amortized under the straight-line single option method prescribed

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

by SFAS 123. We expect that our adoption of FAS 123(R) in 2006 will have a material impact on our results of operations and net loss per share.

### NOTE B - PROPERTY, PLANT AND EQUIPMENT

The Company's property and equipment at December 31, 2005 consists of the following:

Office Equipment	\$6,665
Office Fixtures and Furniture	1,423
	-----
	8,088
Accumulated Depreciation	(3,862)
	-----
	\$4,226
	=====

Depreciation expense included as a charge to income amounted to \$2,274, \$1,078, and \$3,862 for the years ended December 31, 2005 and 2004 and from inception to December 31, 2005, 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:

	2005
	-----
Technology License	\$ 9,250
Website	22,500
Less: accumulated amortization	(25,357)
Impairment of intangible asset	( 6,393)
	-----
Intangible assets, net	\$ -
	=====

Amortization expense included as a charge to income amounted to \$927, \$12,177, and \$25,357 for the years ended December 31, 2005 and 2004, and the period from inception to December 31, 2005, respectively. In December 2005, the Company determined it was necessary to record an impairment charge related to our intangible asset totaling \$6,393, which was charged to operations during the year ended December 31, 2005.

F-16

### NOTE D - ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities at December 31, 2005 are as follows:

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

Accrued penalty for late registration of shares	\$2,061,683
Accounts payable & accrued liabilities	475,030
Insurance contract payable	18,000
Accrued interest	9,098
	-----
Total	\$2,563,811
	=====

### NOTE E - PENALTY FOR LATE REGISTRATION OF SHARES

During the fiscal year December 31, 2005, the Company accrued the issuance of 5,242,307 shares of common stock and warrants to purchase an additional 2,064,187 shares of common stock pursuant to a penalty calculation with regard to the late registration of shares sold in a private placement in October 2004.

In October 2004, we completed a private placement sale of shares of our common stock and warrants to purchase additional shares of common stock. We issued in the private placement an aggregate of 19,600,000 shares of our common stock and warrants to purchase 9,800,000 shares of our common stock. We agreed to register these shares along with the shares underlying these warrants within ninety days from the closing date of the transaction, or we would incur a penalty equivalent to an additional 2% of the shares and warrants to be registered for every 30 days that we fail to complete this registration. This penalty amounts to an aggregate of 461,200 shares and 181,600 warrants per 30 day period until such a time as this registration statement is made effective. As of December 31, 2005, we are required to issue an additional 5,242,307 shares of common stock and warrants to purchase an additional 2,064,187 shares of common stock. At the time these liabilities were incurred, the shares were valued at \$1,991,923 and the warrants were valued at \$638,838. The shares were valued at the market price of the Company's common stock at the time the liabilities were incurred. The warrants were valued utilizing the Black-Scholes valuation model. The aggregate amount of \$2,630,761 was charged to operations as cost of Penalty for late registration of shares during the year ended December 31, 2005.

The shares and warrants were re-valued at December 31, 2005, and the result of this re-valuation was to decrease the value of the shares by \$314,385 and to decrease the value of the warrants by \$254,693. These decreases were credited to other (income) expense during the year ended December 31, 2005. At December 31, 2005, the fair value of the common stock issuable under the penalty for late registration of shares is \$1,677,538, and the fair value of the warrants issuable under the penalty for late registration of shares is \$384,145. These amounts appear as current liabilities on the Company's condensed consolidated balance sheet at December 31, 2005.

As the liability for these penalty shares and warrants must be settled by the delivery of registered shares and the delivery of the registered shares is not controlled by the Company, pursuant to EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock", the net value of the shares and warrants at the date of issuance was recorded as a liability on the balance sheet and the change in fair value from the date of issuance to December 31, 2005 has been included in other income (expense). Upon the registration statement being declared effective, the fair value of the warrant on that date will be reclassified to equity.

We anticipate completing the registration of these shares during the quarter ended June 30, 2006, but expect that an obligation to issue approximately 2,136,893 additional shares and 841,413 additional warrants at an aggregate cost of approximately \$840,000 will be incurred during the period January 1, 2006 to June 30, 2006.

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

### NOTE F - RELATED-PARTY TRANSACTIONS

#### Employment Agreements

-----

#### PRESIDENT AND CHIEF EXECUTIVE OFFICER:

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

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

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

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

Under the change of control agreement, Mr. Wilhelm shall be entitled to a continuation of his base salary for a period of 18 months following an involuntary termination, which means, at any time within that period which is one-year from the change of control date (including such date), the termination of the employment of Mr. Wilhelm (i) by the Company without cause or (ii) due to

F-17

constructive termination, as such terms are defined in the change of control agreement. Further, in the event of an involuntary termination, the agreement provides that the registrant shall pay Mr. Wilhelm a lump sum amount in cash, equal to the sum of (i) any unpaid incentive compensation which has been allocated or awarded to Mr. Wilhelm for a completed fiscal year or other measuring period preceding the date of involuntary termination under any annual or long-term incentive plan and which, as of the date of involuntary termination, is contingent only upon the continued employment of Mr. Wilhelm to a subsequent date, and (ii) a pro rata portion to the date of involuntary termination of the aggregate value of all contingent incentive compensation awards to Mr. Wilhelm for all then uncompleted periods under any such plan. Further, 100% of the unvested portion of each outstanding stock option granted to Mr. Wilhelm shall be accelerated so that they become immediately exercisable upon the date of involuntary termination.

Under the severance agreement, Mr. Wilhelm shall be entitled to a continuation of his base salary for a period of 18 months following an involuntary termination, which means the termination of the employment of Mr. Wilhelm (i) by the Company without cause or (ii) due to constructive termination, as such terms are defined in the severance agreement. Further, in the event of an involuntary termination, the agreement provides that the registrant shall pay Mr. Wilhelm an amount equal to the amount of executive incentive pay (bonus) that he would have

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

received for the year in which the involuntary termination occurred had he met one hundred percent (100%) of the target for such incentive pay. Also, under this agreement, 100% of the unvested portion of each outstanding stock option granted to Mr. Wilhelm shall be accelerated so that they become immediately exercisable upon the date of involuntary termination.

### CHIEF FINANCIAL OFFICER:

Pursuant to our employment agreement with John Fermanis, our Chief Financial Officer, dated February 15, 2005, we paid a salary of \$60,000 until the Company completed a financing of \$500,000 or more. This occurred on March 4, 2005 when the Company completed a Tender Offer for warrants totaling \$1,190,857 net of fees. From March 4, 2005, until December 31, 2005, we will pay an annual salary of \$85,000. Thereafter, we will pay an annual salary of \$98,000 for the second year ending December 31, 2006 and an annual salary of \$112,000 for the third year ending December 31, 2007. Mr. Fermanis' salary is payable in regular installments in accordance with the customary payroll practices of the Company. Mr. Fermanis also receives 100,000 shares of the Company's common stock, which are earned at the rate of 1/12 or 8,333 per month beginning January 2005. The Company charges to operations the market value of these shares as of the first day of each month. For the twelve months ended December 31, 2005, the Company charged \$41,416 to operations for the issuance of 100,000 shares to Mr. Fermanis. This amount is carried in accrued liabilities at December 31, 2005.

### Proprietary Rights Agreement

-----

In December 2002, the Company entered into a royalty-free license agreement with its two founders and largest shareholders. Under the terms of the license agreement, the licensors grant to the Company an exclusive license to use and sublicense certain patents, medical applications, and other technologies developed by the licensors. The Company's obligations under the license agreement include (i) reasonable efforts to protect any licensed patents or other associated property rights; (ii) reasonable efforts to maintain confidentiality of any proprietary information; (iii) upon the granting by the U. S. Food and Drug Administration to the Company the right to market a product, the Company will maintain a broad form general liability and product liability insurance.

In February 2005, Drs. Witten and Harris executed assignment documents in which, for good and valuable consideration, patent applications and patents developed by them were assigned to ImmuneRegen BioSciences, Inc. The assignment documents included all of the patents and patent applications which were included in and covered by the licensing agreement, as amended. Drs. Witten and Harris have also assigned all proprietary technology developed at ImmuneRegen subsequent to the execution of the February 2005 assignment documents.

### 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 I).



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

### Notes Payable

-----

During the twelve months ended December 31, 2005, the Company converted notes payable and accrued interest to Company shareholders in the aggregate amount of \$65,003 into 232,153 shares of the Company's common stock at a price of \$0.28 per share (see Note G).

#### NOTE G - NOTES PAYABLE

During the year ended December 31, 2005, the Company settled in full three (3) notes payable aggregating \$80,000. Payment was made by converting one (1) note in the amount of \$65,003 into 232,153 shares of the Company's common stock, and by paying cash in the amount of \$14,997 in satisfaction of the remaining two (2) notes. The Company has no notes payable outstanding at December 31, 2005.

#### NOTE H - 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, 2005, the Company has 69,436,319 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 costs and fees. In July, 2003, the Company issued 2,368,130 in connection with the Company's acquisition and merger with GPN Network, Inc. (see Note A.)

During the year ended December 31, 2004, the Company issued an aggregate of 5,481,280 shares of common stock to consultants for services in the amount of \$2,877,872. All valuations of common stock issued for services were based upon the value of the services rendered, which did not differ materially from the fair value of the Company's common stock during the period the services were rendered. In addition, the Company issued 300,000 shares of common stock as with a fair value of \$36,000 as interest on a note payable. In addition, in conjunction with a private placement of stock (see below), the Company issued 6,855,062 shares of common stock in exchange for \$ 630,591 of previously incurred debt and accrued interest. In addition, the Company issued 590,000 shares of common stock in exchange for \$65,000 of previously issued debt. Total debt exchanged for stock during the year ended December 31, 2004 was \$695,591 of

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

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

F-19

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

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

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

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

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

The accrued penalties in connection with the issuance of the shares of common

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

stock is included in accounts payable and accrued expenses at December 31, 2005.

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

For the year ended December 31, 2005 the change in fair value of the warrant issued with registration rights decreased by approximately \$254,693 to \$384,145 at December 31, 2005 and is recognized in other income (expense).

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

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

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

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

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

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

### NOTE I - 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

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

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.

F-20

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	Weighted Average Remaining Contractual Life (years)
\$25.00	63,212	4.24	\$25.00	63,212	4.24
0.31	1,000	4.95	0.31	1,000	4.95
0.33	103,030	4.61	0.33	103,030	4.61
0.44	150,000	4.34	0.44	150,000	4.34
	317,242			317,242	
	317,242			317,242	

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

	Number of Shares	Weighted Average Price Per Share
Outstanding at December 31, 2003	63,212	25.00
Granted	--	--
Exercised	--	--
Canceled or expired	--	--
	63,212	\$25.00
Outstanding at December 31, 2004	63,212	\$25.00
Granted	254,030	0.39
Exercised	--	--
Canceled or expired	--	--
	317,242	\$ 5.30
	317,242	\$ 5.30

### 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

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

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)	Exercise Price	Number Exercisable	Weighted Average Remaining Contractual Life (years)
\$ .05-.10	519,780	3.38	\$.05-.10	519,780	3.38
.125-.21	911,819	3.46	.125-.21	911,819	3.46
.25-.56	9,271,405	3.57	.25-.56	9,271,405	3.57
1.00	867,311	2.08	1.00	867,311	2.08
2.00	46,550	3.21	2.00	46,550	3.21
	11,616,865	3.44		11,616,865	3.44
	=====	=====		=====	=====

F-21

Transactions involving warrants are summarized as follows:

	Number of Shares (post-split)	Weighted Average Price Per Share (post-split)
Outstanding at January 1, 2004	832,510	\$ .82
Granted	16,831,199	.47
Exercised	(6,600,778)	.50
Canceled or expired	--	--
Outstanding at December 31, 2004	11,062,931	.48
Granted	757,464	.44
Exercised	(80,000)	.05
Canceled or expired	(123,530)	2.00
Outstanding at December 31, 2005	11,616,865	\$ .46
	=====	=====

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:

	2005	2004
Significant assumptions (weighted-average):		
Risk-free interest rate at grant date	3.75%	3.75%
Expected stock price volatility	93% to 179%	163% to 262%
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 \$279,711 and \$406,571 during the years

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

ended December 31, 2005 and 2004, respectively.

The Company also capitalized financing costs of \$0 and \$397,394 for warrants granted in connection with placement of convertible debentures for the years ended December 31, 2005 and 2004, respectively.

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

F-22

share (post-split) were issued under the Secured Note Warrants. The value of these warrants was computed utilizing the Black-Scholes valuation model, and the total value of these warrants, or \$112,562 was charged to operations during the twelve months ended December 31, 2004.

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

In April through June 2004, the Company issued warrants to purchase 32,500 shares (post-split) at price ranging from \$0.25 to \$2.00 to consultants for

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

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.

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

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

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

F-23

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

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

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

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

### NOTE J - COMMITMENTS AND CONTINGENCIES

#### Office Leases

-----

Our corporate headquarters are currently located at 4021 N. 75th Street, Suite 201, Scottsdale, Arizona 85251, where we have leased approximately 1,800 square feet of office space through September 30, 2007. Our rent expense is \$2,320 per month in year one and will increase to \$2,380 in year two. We believe that our facilities are adequate for our current needs and suitable additional or substitute space will be available in the future to replace our existing facilities, if necessary, or accommodate expansion of our operations.

Rent expense amounted to \$27,785 for the years ended December 31, 2005, \$41,051 for the year ended December 31, 2004, and \$102,939 for the period from October 30, 2002 (inception) through December 31, 2005.

#### Employment and Consulting Agreements

-----

The Company has employment agreements with all of its President and Chief Executive Officer (See Note F). In addition to salary and benefit provisions,



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

the agreements include non-disclosure and confidentiality provisions for the protection of the Company's proprietary information. The Company also has a severance agreement and a change of control agreement in place with its President and Chief Executive Officer.

The Company also has an employment agreement with its Chief Financial Officer which provide salary and benefit provisions.

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

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 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.

The judgment was subsequently settled in full for a cash payment of \$35,107 paid on August 2, 2005 releasing us from all obligations under the judgment.

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.

F-24

### NOTE K - INCOME TAXES

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

For income tax reporting purposes, the Company's aggregate unused net operating losses approximate \$4,970,000 which expire through 2026, subject to limitations of Section 382 of the Internal Revenue Code, as amended. The deferred tax asset related to the carryforward is approximately \$1,740,000. The Company has provided a valuation reserve against the full amount of the net operating loss

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

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, 2005 are as follows:

Non Current:

Net operating loss carryforward	\$1,740,000
Valuation allowance	(1,740,000)
	-----
Net deferred tax asset	\$ --
	=====

### NOTE L - LOSSES PER COMMON SHARE

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

	2005	2004	For the Period From October 30, 2002 (Date of Inception) Through December 31, 2005
	-----	-----	-----
Net loss available to common shareholders	\$ (4,591,107)	(5,305,407)	\$ (11,799,134)
	=====	=====	=====
Basic and fully diluted loss per share	\$ (0.07)	\$ (0.16)	\$ (0.30)
	=====	=====	=====
Weighted average common shares outstanding	67,691,598	33,510,168	38,934,503
	=====	=====	=====

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.

At December 31, 2005 and 2004, there were 11,680,077 and 11,380,173, respectively, shares of common stock issuable subject to stock options and warrants. These shares were excluded from the computation of diluted net loss per share as their effect was antidilutive. If we had reported net income, the calculation of these per share amounts would have included the dilutive effect of these common stock equivalents using the treasury stock method.

### NOTE M - SUBSEQUENT EVENTS

On March 10, 2006 we issued to our Chief Financial Officer, John N. Fermanis, 100,000 registered common stock per the terms of his employment agreement.

From the period of January 1, 2005 to March 20, 2005, we accrued the issuance of 1,214,493 shares of common stock and warrants to purchase an additional 478,213 shares of common stock pursuant to a penalty calculation with regard to the late registration of shares sold in a private placement in October 2004. As of March 20, 2005, we are required to issue an additional 6,456,800 shares of common stock and additional warrants to purchase 2,542,400 shares of common stock pursuant to the late registration penalty.

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

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

None.

### ITEM 8A. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.  
-----

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

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

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, 2005 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### ITEM 8B. OTHER INFORMATION

None.

48

## PART III

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

Our directors and executive officers are:

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

Name	Age	Position
Michael K. Wilhelm	38	President, Chief Executive Officer and Director
John N. Fermanis	52	Chief Financial Officer
Mark L. Witten, Ph.D.	52	Director
Theodore E. Staahl, M.D.	61	Director

MICHAEL K. WILHELM, PRESIDENT, CHIEF EXECUTIVE OFFICER AND DIRECTOR. Mr. Wilhelm has served as our President and Chief Executive Officer and on our Board of Directors since July 2003 and as President and Chief Executive Officer of ImmuneRegen BioSciences, Inc. since December 2002 and on its Board of Directors since November 2002. Mr. Wilhelm has been actively involved in the financial industry since 1990. After leaving the brokerage industry, Mr. Wilhelm founded Foresight Capital Partners in July 1996, a company designed to identify early stage companies with above average growth potential and assist them in reaching the next stage of development. In working with these companies, Mr. Wilhelm took an active role, provided advisory services and facilitated financing for continued growth and development. Mr. Wilhelm was Managing Director of Foresight Capital Partners until December 2002. Mr. Wilhelm works on average 70 hours per week.

JOHN N. FERMANIS, CHIEF FINANCIAL OFFICER. Mr. Fermanis was appointed as our Chief Financial Officer, effective as of December 22, 2004. Mr. Fermanis is a co-founder of AMPS Wireless Data, Inc., a privately held Arizona corporation founded in 1998, where he served as Chief Financial Officer from May, 2001 to October, 2004. Mr. Fermanis had overall financial responsibility at AMPS and was instrumental in raising over \$5 Million in venture capital. From 1997 to 2001, he held the position of Treasury Manager for Peter Piper, Inc., a national restaurant chain headquartered in Scottsdale, Arizona, where he was responsible for managing a \$25 Million revolving line of credit and cash concentration and disbursement for a company with over \$100 Million annual sales. Mr. Fermanis has over 18 years of financial management experience with both the American Express Corporation and Citigroup in New York City. Mr. Fermanis holds a Bachelor of Arts degree from the S.U.N.Y. at Stony Brook and attended Pace University's Graduate School of Management in New York City. Mr. Fermanis works on average 60 hours per week.

THEODORE E. STAAHL, M.D., DIRECTOR. Dr. Staahl has served on our Board of Directors since April 2003. Dr. Staahl is employed at the Cosmetic, Plastic and Reconstructive Surgery Center, a company which he founded in 1978. Dr. Staahl's professional training was received at the University of Illinois and the University of Wisconsin and is board certified by the American Board of Facial, Plastic and Reconstruction Surgeons, the Board of Cosmetic Surgeons and the American Board of Head and Neck Surgeons. Dr. Staahl has presented papers at national and international meetings on hair transplant, rhinoplasty and cleft lip deformities. Dr. Staahl devotes on average 3 hours per week to our business.

MARK L. WITTEN, PH.D., DIRECTOR. Dr. Witten has served on our Board of Directors since July 2003 and has served on the Board of Directors for ImmuneRegen BioSciences, Inc. since November 2002. Dr. Witten served as a research scientist for ImmuneRegen BioSciences, Inc. from July 2003 to February 2006. Dr. Witten has served as a Research Professor at the University of Arizona since July 2000. Since July 1998 Dr. Witten has served as the Director of the Joan B. and Donald R. Diamond Lung Injury Laboratory in the Department of Pediatrics at the University of Arizona College of Medicine. Dr. Witten obtained his Ph.D. from Indiana University in 1983 with a double major in physiology and exercise physiology. He conducted a post-doctoral fellowship in Respiratory Sciences at the University of Arizona College of Medicine from 1983 to 1988. He then spent two years as an Assistant Biologist at Massachusetts General Hospital and Instructor in Medicine at Harvard Medical School. He returned to The University of Arizona College of Medicine in 1990. Dr. Witten has authored over 200 published manuscripts, book chapters and abstracts. Dr. Witten devotes on

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

average 3 hours per week to our business.

There are no family relationships among the directors and executive officers.

### COMPLIANCE WITH SECTION 16(A) OF THE SECURITIES EXCHANGE ACT OF 1934

Section 16(a) of the Securities Exchange Act of 1934 requires the Company's directors and executive officers and persons who own more than ten percent of a registered class of the Company's equity securities to file with the SEC initial reports of ownership and reports of changes in ownership of Common Stock and other equity securities of the Company. Officers, directors, and greater than ten percent stockholders are required by SEC regulations to furnish the Company with copies of all Section 16(a) forms they file. To the

49

Company's knowledge, based solely on review of the copies of such reports furnished to us during the fiscal year ended December 31, 2005, all Section 16(a) filing requirements applicable to the Company's officers, directors and greater than ten percent stockholders were satisfied by such persons.

### COMMITTEES OF THE BOARD OF DIRECTORS

Our Board of Directors does not maintain a separate audit, nominating or compensation committee. Functions customarily performed by such committees are performed by our board of directors as a whole. We are not required to maintain such committees under the applicable rules of the Over-the-Counter Bulletin Board. None of our independent directors qualify as an "audit committee financial expert" as that term is defined in Item 401(e) of Regulation S-B.

### ITEM 10. EXECUTIVE COMPENSATION

The following table sets forth information concerning the compensation earned by our Chief Executive Officer and each of the other executive officers who served during the year ended December 31, 2005, and whose annual salary and bonus during the fiscal years ended December 31, 2003, 2004 and 2005 exceeded \$100,000 (the "Named Executive Officers").

NAME AND PRINCIPAL POSITION	YEAR	ANNUAL COMPENSATION SALARY (\$)	BO
Michael K. Wilhelm(1) Chief Executive Officer and President	2005	275,000	
	2004	175,000	
	2003	125,000	
John N. Fermanis Chief Financial Officer (4)	2005	161,416(5)	
	2004	0	
	2003	0	

(1) Michael K. Wilhelm has served as Chief Executive Officer and President of IR BioSciences Holdings, Inc. since July 2003 when the Reorganization was completed. Prior to the completion of the Reorganization, Mr. Wilhelm served as Chief Executive Officer and President of ImmuneRegen

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

BioSciences, Inc. since December 2002. Mr. Wilhelm's compensation is reported in the table with respect to his positions at both IR BioSciences Holdings, Inc. and ImmuneRegen BioSciences, Inc. for the years ended December 31, 2003, 2004 and 2005.

- (2) Reflects the value of 80,811 warrants granted to Michael K. Wilhelm as performance bonuses per his employment agreement. In May 2005, the Company issued a warrant to Mr. Wilhelm to purchase 80,811 shares (post-split) of common stock at a price of \$0.30 per share (post-split). The Company valued these warrants using the Black-Scholes model, and charged the amount of \$28,870 to operations during the twelve months ended December 31, 2005.
- (3) Reflects the value of 948,980 warrants granted to Michael K. Wilhelm as performance bonuses. In May 2004, the Company issued a warrant to Mr. Wilhelm 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 to operations during the twelve months ended December 31, 2004. In October 2004, the Company issued a warrant to Mr. Wilhelm 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.
- (4) John N. Fermanis served as Chief Financial Officer from December 2004.
- (5) Reflects the value of 100,000 shares of common stock issued to John N. Fermanis in the three months ended March 31, 2005 as part of compensation per his employment agreement. For the twelve months ended December 31, 2005, the Company charged \$35,000 to operations for the issuance of these 100,000 shares to Mr. Fermanis.

Also reflects the value of an additional 100,000 shares of common stock issued to John N. Fermanis as part of compensation per his employment agreement. The shares were earned at the rate of 1/12 or 8,333 per month beginning January 2005. The Company charged to operations the market value of these shares as of the first day of each month. For the twelve months ended December 31, 2005, the Company charged \$41,416 to operations for the issuance of 100,000 shares to Mr. Fermanis.

50

- (6) Reflects the value of 12,500 warrants granted to John N. Fermanis as performance bonuses per his employment agreement. In May 2005, the Company issued a warrant to Mr. Fermanis to purchase 12,500 shares of common stock at a price of \$0.31 per share. The Company valued these warrants using the Black-Scholes model, and charged the amount of \$4,590 to operations during the twelve months ended December 31, 2005.

### COMPENSATION OF DIRECTORS

STANDARD ARRANGEMENTS. Directors currently receive no cash compensation from IR BioSciences Holdings, Inc. for their services as members of the Board or for attendance at committee meetings. Members of the Board are reimbursed for some expenses in connection with attendance at Board and committee meetings.

OTHER ARRANGEMENTS. We may from time to time issue warrants to executives and directors for fulfilling certain performance goals.

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

On December 16, 2002 we entered into consulting agreements Mark Witten, our chief research scientist and director. The consulting agreement is on a month-to-month basis. Under the terms of this agreement, Dr. Witten agrees to place at the disposal of us his judgment and expertise in the area of acute lung injury. In consideration for these services, we agree to pay Dr. Witten a non-refundable fee of \$5,000 per month. This contract was terminated effective February 1, 2006.

### EMPLOYMENT AGREEMENTS

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

- (i) A target incentive bonus in cash and/or stock if we consummate a transaction with any unaffiliated third party such as an equity or debt financing, acquisition, merger, strategic partnership or other similar transaction.
- (ii) A one time grant of an incentive option to purchase 103,030 shares of the Company's Common Stock, at an exercise price equal to the fair market value per share on the date option is granted and a nonstatutory option to purchase 1,896,970 shares at such time that the Company's 2003 Stock Plan is amended to authorize additional shares.

In connection with Mr. Wilhelm's new employment agreement, we also entered into a change of control agreement and a severance agreement with him on August 10, 2005. Under the change of control agreement, Mr. Wilhelm shall be entitled to a continuation of his base salary for a period of 18 months following an involuntary termination, which means, at any time within that period which is one-year from the change of control date (including such date), the termination of the employment of Mr. Wilhelm (i) by us without cause or (ii) due to constructive termination, as such terms are defined in the change of control agreement. Further, in the event of an involuntary termination, the agreement provides that we shall pay Mr. Wilhelm a lump sum amount in cash, equal to the sum of (i) any unpaid incentive compensation which has been allocated or awarded to Mr. Wilhelm for a completed fiscal year or other measuring period preceding the date of involuntary termination under any annual or long-term incentive plan and which, as of the date of involuntary termination, is contingent only upon the continued employment of Mr. Wilhelm to a subsequent date, and (ii) a pro rata portion to the date of involuntary termination of the aggregate value of all contingent incentive compensation awards to Mr. Wilhelm for all then uncompleted periods under any such plan. Further, 100% of the unvested portion of each outstanding stock option granted to Mr. Wilhelm shall be accelerated so that they become immediately exercisable upon the date of involuntary termination.

Under the severance agreement, Mr. Wilhelm shall be entitled to a continuation of his base salary for a period of 18 months following an involuntary termination, which means the termination of the employment of Mr. Wilhelm (i) by us without cause or (ii) due to constructive termination, as such terms are defined in the severance agreement. Further, in the event of an involuntary termination, the agreement provides that we shall pay Mr. Wilhelm an amount equal to the amount of executive incentive pay (bonus) that he would have received for the year in which the involuntary termination occurred had he met

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

one hundred percent (100%) of the target for such incentive pay. Also, under this agreement, 100% of the unvested portion of each outstanding stock option granted to Mr. Wilhelm shall be accelerated so that they become immediately exercisable upon the date of involuntary termination.

51

On February 15, 2005, we entered into an employment agreement with John N. Fermanis, our Chief Financial Officer. The employment agreement expires on December 31, 2007, unless terminated earlier pursuant to the terms of the agreement. Under the terms of the employment agreement, Mr. Fermanis is entitled to a base salary of \$60,000 until the company completed a funding of \$500,000 or more which occurred on March 4, 2005, at which time the base salary was increased to \$85,000 until December 31, 2005. Thereafter, the second year salary will be \$98,000 per annum and the third year will be \$112,000 per annum. Severance provisions include two months salary for termination for cause and six months salary for constructive termination. This agreement also provides for the following various bonus incentives:

- (i) A quarterly discretionary bonus based upon our performance in the previous quarter. This discretionary bonus will be in the form of stock options.
- (ii) A quarterly five-year warrant to purchase up to 12,500 shares of our common stock at 75% of the fair market value of the stock on the date the warrant is granted.

### STOCK OPTIONS

We issued 253,030 stock options to our Chief Executive Officer, Michael Wilhelm, during the fiscal year ended December 31, 2005.

### OPTIONS GRANTED IN THE YEAR ENDED DECEMBER 31, 2005

The following table sets forth information concerning individual grants of stock options in 2005 to the Named Executive Officers:

Name	Individual Grants				Potential Real	
	Number of Securities Underlying Options Granted	Percent of Total Options Granted to Employees	Exercise or Base Price Per Share	Expiration Date	Value at Ass	Annual Rates of Price Appreci for Option Te
Michael K. Wilhelm	103,030	40.6%	\$ 0.33	8/10/10	\$ 9,394	\$
	150,000	59.0	0.44	5/20/10	18,235	

(1) In order to comply with the rules of the SEC, we are including the gains or "option spreads" that would exist for the respective options we granted to the Named Executive Officers. We calculated these gains by assuming an annual compound stock price appreciation of 5% and 10% from the date of the option grant until the termination date of the option, which is the fifth



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

anniversary of the grant date. These gains do not represent our estimate or projection of the future price of the ordinary shares.

### OPTIONS EXERCISES AND OPTIONS VALUES FOR YEAR ENDED DECEMBER 31, 2005

The following table sets forth information concerning option exercises in 2005 and option values as of December 31, 2005 to the Named Executive Officers:

Name	Shares Acquired on Exercise	Value Realized	Number of Securities Underlying Unexercised Options at Fiscal Year-End		Value of Unexercised In-the-Money Options at Fiscal Year-End	
			Exercisable	Un-exercisable	Exercisable	Un-exercisable
Michael K. Wilhelm	--	\$ --	253,030	--	\$ --	\$ --

(1) The value of unexercised "in-the-money" options is based on a price per share of \$0.32, which was the price of a share as quoted on the OTC Bulletin Board at the close of business on December 31, 2005, minus the exercise price, multiplied by the number of shares underlying the option.

52

### 2003 STOCK OPTION, DEFERRED STOCK AND RESTRICTED STOCK PLAN

We 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 3,600,000 shares. The options will have a term not to exceed ten years from the date of the grant.

At December 31, 2005, an aggregate of 254,030 stock options were outstanding under the Plan at prices ranging from \$0.31 to \$0.44 per share. At such date, there were 201,996 stock options available for grant. Further, the Board approved a one time grant of an incentive option to our Chief Executive Officer to purchase 1,896,970 shares at the fair market value per share on the date the option is granted. The options shall be granted at such time that the Company's 2003 Stock Plan is amended to authorize additional shares.

During the fiscal year ended December 31, 2005, 150,000 discretionary incentive stock options were granted to our Chief Executive Officer, Michael K. Wilhelm, per his employment agreement. The options have an exercise price of \$0.44 and a term of five years. Additionally, the Board approved a one time grant of an incentive option to our Chief Executive Officer to purchase 103,030 shares of the Company's Common Stock. The options have an exercise price of \$0.33 and a term of five years. Further, our Board of Directors approved a one time grant of a nonstatutory option to purchase 1,896,970 shares at the fair market value per share on the date the option to our Chief Executive Officer, Michael K. Wilhelm. These warrants will be granted such time that the Company's 2003 Stock Plan is amended to authorize additional shares.

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

Through December 31, 2003, we had granted, prior to the merger with ImmuneRegen BioSciences, Inc., options to purchase 63,212 shares of our common stock at a weighted average exercise price of \$25.00 per share to certain employees and consultants that are exercisable over various periods through March 2010. These stock options were granted outside of our 2003 Stock Option, Deferred Stock and Restricted Stock Plan.

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

The following table sets forth information regarding the beneficial ownership of our common stock as of March 10, 2006 by: (i) all those known by IR BioSciences Holdings, Inc. to be beneficial owners of more than five percent of its common stock, (ii) each director and executive officer of IR BioSciences Holdings, Inc., and (iii) all executive officers and directors of IR BioSciences Holdings, Inc. as a group. Unless indicated below, the address for each listed stockholder is c/o IR BioSciences Holdings, Inc., 4021 North 75th Street, Suite 201, Scottsdale, Arizona 85251.

Name	Beneficial Ownership (1)	% of Shares (2)
Michael K. Wilhelm	8,132,814(3)	11.4
John N. Fermanis	117,500(4)	*
Mark L. Witten	9,501,138(5)	13.5
Theodore Staahl	3,489,464(6)	5.0
David T. Harris	5,066,138	7.3
All executive officers and directors as a group (4 persons)	21,240,916(7) =====	29.3 =====

\* Less than one percent.

1. Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission. In general, a person who has voting power or investment power with respect to securities is treated as beneficial owner of those securities. Common shares subject to options and warrants currently exercisable or exercisable within 60 days of March 10, 2006 count as outstanding for computing the percentage beneficially owned by the person holding these options or warrants.
2. Percentages are based on 69,536,319 shares of common stock outstanding as of March 20, 2006.
3. Includes 1,788,718 shares of common stock underlying warrants and 253,030 shares of common stock underlying options that are currently exercisable or exercisable within 60 days of March 10, 2006. Includes 4,066,138 shares of common stock purchase warrants issued to Foresight Capital Partners, a company controlled by Michael Wilhelm that are currently exercisable or exercisable within 60 days of March 10, 2006.
4. Includes 17,500 shares of common stock underlying warrants that are currently exercisable or exercisable within 60 days of March 10, 2006. Includes 100,000 shares of Common Stock that have been approved by the Board of Directors for issuance; however, have not yet been issued.
5. Includes 712,000 shares of common stock underlying warrants that are currently exercisable or exercisable within 60 days of March 10, 2006.
6. Includes 238,000 shares of common stock underlying warrants that are

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

currently exercisable or exercisable within 60 days of March 10, 2006. Includes 93,300 shares of Common Stock that have been approved by the Board of Directors for issuance; however, have not yet been issued.

7. Includes 2,721,218 shares of common stock underlying warrants and 253,030 shares of common stock underlying options that are currently exercisable or exercisable within 60 days of March 10, 2006. Includes 4,101,138 shares of common stock underlying third party warrants that are currently exercisable or exercisable within 60 days of March 10, 2006.

### SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

The following table provides information as of December 31, 2005 regarding compensation plans (including individual compensation arrangements) under which equity securities of our company are authorized for issuance. All share information included in this table has been adjusted to reflect a 2-for-1 forward stock split of our common stock that was effected in April 2004.

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted- average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under compensation plans (excluding securities reflected in column (c)) (c)
Equity compensation plans approved by security holders.....	254,030 (1)	\$0.39	201,96
Equity compensation plans not approved by security holders.....	11,680,077 (2)	\$0.59	-
Total.....	11,934,107 =====		201,96 =====

- (1) Represents 254,030 stock options at a weighted average price of \$0.39 outstanding under our 2003 Stock Option, Deferred Stock and Restricted Stock Plan.
- (2) Represents 11,616,865 stock purchase warrants at a weighted average price of \$0.46 and 63,212, options at a weighted average exercise price of \$25.00.
- (3) Represents 201,996 shares are available for future issuance under our 2003 Stock Option, Deferred Stock and Restricted Stock as of the date hereof.

Further, the Board approved a one time grant of an incentive option to our Chief Executive Officer, Michael K. Wilhelm, to purchase 1,896,970 shares at the fair market value per share on the date the option is granted. The options shall be granted at such time that the Company's 2003 Stock Plan is amended to authorize additional shares.

### WARRANTS

The following table summarizes the changes in warrants outstanding

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

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.

	Number of Shares (post-split)	Weighted Average Price Per Share (post-split)
	-----	-----
Outstanding at January 1, 2004	832,510	\$ .82
Granted	16,831,199	.47
Exercised	(6,600,778)	.50
Canceled or expired	--	--
	-----	-----
Outstanding at December 31, 2004	11,062,931	.48
Granted	757,464	.44
Exercised	(80,000)	.05
Canceled or expired	(123,530)	2.00
	-----	-----
Outstanding at December 31, 2005	11,616,865	\$ .46
	=====	=====

A description of our warrant arrangements and issuances are included in our financial statements for the year ended December 31, 2005 under "Note I - Stock Options and Warrants,"

54

### ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

#### IMMUNEREGEN BIOSCIENCES, INC.

ImmuneRegen BioSciences, Inc. is a wholly-owned subsidiary of IR BioSciences Holdings, Inc. IR BioSciences Holdings, Inc. and ImmuneRegen BioSciences, Inc. have interlocking executive positions and share common ownership.

#### IMMUNEREGEN BIOSCIENCES ASIA PTE. LTD.

ImmuneRegen BioSciences Asia PTE. LTD. ("ImmuneRegen Asia"), a Singaporean company, is an affiliate of IR BioSciences Holdings, Inc. Approximately 94% of the company is owned equally between our Chief Executive Officer and Chairman, Michael K. Wilhelm, and our Director, Mark Witten. IR BioSciences Holdings, Inc. holds less than 1% ownership in the company. For the three month period ended December 31, 2005, we incurred no expenses. For the period of inception (October 30, 2002) to December 31, 2005, we incurred expenses totaling approximately \$133,781, \$114,660 on a Singapore-based consultant and \$19,121 on travel regarding corporate development and the attendance of symposiums and conferences.

In November 2003, based on observations made during early preclinical animal model studies we approached Ever Progressing System PTE LTD ("EPS"), a Singapore based contract research organization (CRO), in an attempt to increase our market presence, attract potential funding sources for our research and development efforts and to identify and receive governmental grants. EPS advised us that a presence in Singapore would be desirable if we wanted to pursue such efforts in Singapore and elsewhere in Asia.

Acting on their advice, we incorporated, under the Singapore Companies Act, ImmuneRegen Asia on June 5, 2004 and retained a Singapore-based consultant to assist us in (i) the development and set-up of our Singapore corporation;

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

(ii) increasing our visibility in Asia through attendance of conferences, meetings, symposiums, etc.; (iii) reaching out to contacts in various governmental organizations; and, (iv) contact bankers, institutional and private sources of funds for start-up costs, research and development and working capital related to ImmuneRegen Asia.

Between November 2003 and January 2005, we held discussions with the Economic Development Board of Singapore ("EDB") to assist in establishing a research and development and clinical trials presence in Singapore. In October 2004, our Singapore-based consultant and representatives of ImmuneRegen BioSciences, Inc. met with several members of Thailand's Department of Disease Control, Ministry of Public Health in Bangkok. Also in October 2004, our Singapore-based consultant met with various departments of the Philippines Department of Health in Manila.

By April 2005, our efforts to further discussions with the EDB and other governmental agencies and to secure adequate funding had proven unsuccessful. At that time our Board of Directors opted to terminate the Singapore-based consultant, dissolve ImmuneRegen Asia and focus solely on our United States operations. We have since abandoned all discussions with EPS the EDB and other governments in Asia regarding our research and development activities.

Dissolution of ImmuneRegen Asia of which we own less than a 1% interest, has been initiated pursuant to the requirements of Section 344 of the Singapore Companies Act. ImmuneRegen Asia has not conducted any business since its creation in May 2004, and is expected to satisfy the requirements for dissolution with completion of the process anticipated in the near future. Upon adequate and sufficient showing to the Singapore Registrar of Companies, ImmuneRegen Asia will be struck off the register of companies and the company will be dissolved. Shareholder and Board approval have occurred and the required documents are being filed with the registrar of companies in Singapore.

### OFFICE LEASE

During the period from December 1, 2002 through August 31, 2004, the Company leased office space from an entity controlled by the our 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.

### INONE CONTRACT

We have 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 Michael Wilhelm, the Company's CEO. 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 our common stock and \$15,000. This Agreement also provides that InOne will bill us 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 our website for one year in exchange for 140,000 shares (post split) of our common stock and \$4,200; (iii) an Agreement dated December 30, 2003 whereby InOne will name and design a logo for respiratory infectious diseases, such as SARS (Viprovex), in

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

exchange for \$5,000 and a warrant to purchase 20,000 shares (post-split) of our common stock at a price of \$0.125; (iv) an Agreement dated December 31, 2003 whereby InOne will name and design a logo for Acute Radiation Syndrome (ARS) medical countermeasure for radiation (Radilex) in exchange for \$5,000 and a warrant to purchase 20,000 shares (post-split) of our common stock at a price of \$0.125.

At December 31, 2005, InOne no longer employs or has any business relationship with the spouse of Mr. Wilhelm.

The amounts due InOne at December 31, 2005 and 2004 are \$0 and \$2,700, respectively.

### RELATED PARTY LOANS

There were no loans to related parties entered into during the fiscal year ended December 31, 2005. Additionally, there were no loans to related parties outstanding at December 31, 2005.

### LICENSE AGREEMENT

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

In February 2005, Drs. Witten and Harris executed assignment documents in which, for good and valuable consideration, patent applications and patents developed by them were assigned to ImmuneRegen BioSciences, Inc. The assignment documents included all of the patents and patent applications which were included in and covered by the licensing agreement, as amended. Drs. Witten and Harris have also assigned all proprietary technology developed at ImmuneRegen subsequent to the execution of the February 2005 assignment documents.

Neither the termination of Dr. Harris' consulting agreement in March 2005 nor the termination of Dr. Witten's consulting agreement in February 2006 have any impact on the license agreement.

### CONSULTING AGREEMENTS

On December 16, 2002 we entered into consulting agreements with David Harris and Mark Witten, who were our two founders and research scientists. The consulting agreements are on a month-to-month basis. Under the terms of these agreements, Messrs. Harris and Witten agreed to place at the disposal of us their judgment and expertise in the area of acute lung injury. In consideration for these services, we agreed to pay each of them a non-refundable fee of \$5,000 per month. In March 2005, Dr. Harris resigned as consultant to us and our subsidiaries. In January 2006, the company received correspondence from Dr. Witten stating that he would terminate his consulting contract if his specific requirements were not met. We subsequently accepted his termination effective February 1, 2006.

Pursuant to consulting agreements entered into with David Harris and Mark Witten, who are our two founders and chief research scientists, during the period from October 30, 2002 (inception) to December 31, 2002, we accrued \$5,000 in consulting fees. During the period from January 1, 2003 to December 31, 2003,

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

we accrued an additional \$120,000 in consulting fees. We had accrued payables collectively due to Drs. Harris and Witten of \$125,000 and \$5,000 as of December 31, 2003 and 2002, respectively. In connection with our recently completed private offering in October 2004, \$90,500 of such amount owed to Dr. Witten converted into 724,000 shares of our common stock and warrants to purchase 362,000 shares of common stock. In October 2004, because Dr. Harris had not taken an active role in the management of the Company, he agreed that he would forgive the amount accrued to him under the Consulting agreement of \$107,500. We accounted for the transaction as a forgiveness of indebtedness under FAS No. 140 during the period ended December 31, 2004.

56

### DUE TO RELATED PARTIES

Pursuant to consulting agreements entered into with David Harris and Mark Witten, who are our two founders and chief research scientists, during the period from October 30, 2002 (inception) to December 31, 2002, we accrued \$5,000 in consulting fees. During the period from January 1, 2003 to December 31, 2003, we accrued an additional \$120,000 in consulting fees. We had accrued payables collectively due to Drs. Harris and Witten of \$125,000 and \$5,000 as of December 31, 2003 and 2002, respectively. In connection with our recently completed private offering in October 2004, \$90,500 of such amount owed to Dr. Witten converted into 724,000 shares of our common stock and warrants to purchase 362,000 shares of common stock. In October 2004, because Dr. Harris had not taken an active role in the management of the Company, he agreed that he would forgive the amount accrued to him under the Consulting agreement of \$107,500. We accounted for the transaction as a forgiveness of indebtedness under FAS No. 140 during the period ended December 31, 2004.

As of August 15, 2004, we had accrued payables due to our President and CEO, Michael Wilhelm, of \$109,374. In connection with our recently completed private offering in October 2004, \$89,500 of such amount was converted into 716,000 shares of common stock and warrants to purchase 358,000 shares of common stock.

### OUTSTANDING LOANS

In January 2003, we were loaned \$15,000 by an accredited investor. Pursuant to the terms of this transaction, we provided this lender with a warrant to purchase 26,939 shares of our common stock at a price \$0.17 per share. The interest rate was 8% per annum. The principal was repaid in March 2005. Interest owed of \$2,410.96 was converted into 19,288 shares of common stock per the term of the note.

Between August 2001 and April 2003 we were loaned money by our President and Chief Executive Officer. We repaid the remaining balance in full for \$4,998 (\$3,900 principal and \$1,097 accrued interest) on April 11, 2005 releasing us from further obligations under the note.

In September 2001, we were loaned \$50,000 by an accredited investor. On June 7, 2005, the remaining note in the principal amount of \$50,000 and all accrued interest of \$15,003 were converted into 232,153 shares of our common stock in accordance with the original terms of the note.

57

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

### ITEM 13. EXHIBITS

#### EXHIBITS

EXHIBIT NUMBER	DESCRIPTION OF EXHIBIT
-----	-----
2.1	Agreement and Plan of Merger dated July 2, 2003 among the Registrant, GPN Acquisition Corporation and ImmuneRegen BioSciences, Inc. (incorporated by reference to exhibit 2 of the Registrant's current report on Form 8-k filed with the Securities and Exchange Commission on July 7, 2003).
3.1	Certificate of Incorporation filed with the Delaware Secretary of State on June 4, 1985 (incorporated by reference to exhibit 3.1 of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(a)	Certificate of Amendment filed with the Delaware Secretary of State on July 16, 1987 (incorporated by reference to exhibit 3.1(a) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(b)	Certificate of Amendment filed with the Delaware Secretary of State on February 3, 1992 (incorporated by reference to exhibit 3.1(b) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(c)	Certificate of Amendment filed with the Delaware Secretary of State on November 23, 1992 (incorporated by reference to exhibit 3.1(c) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(d)	Certificate of Amendment filed with the Delaware Secretary of State on December 15, 1994 (incorporated by reference to exhibit 3.1(d) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(e)	Certificate of Amendment filed with the Delaware Secretary of State on November 7, 1995 (incorporated by reference to exhibit 3.1(e) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(f)	Certificate of Amendment filed with the Delaware Secretary of State on December 30, 1996 (incorporated by reference to exhibit 3.1(f) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.1(g)	Certificate of Amendment filed with the Delaware Secretary of State on November 8, 2000 (incorporated by reference to exhibit 3.1(h) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
3.2	Amended and Restated Bylaws of the Registrant dated as of



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

January 1, 2002 (incorporated by reference to exhibit 3(b) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).

- 4.1 Specimen Common Stock Certificate (incorporated by reference to exhibit 4.1 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).

58

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

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

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).

59

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

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

Exchange Commission on July 20, 2005).

- 10.4(e) Assignment Agreement dated November 7, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Mark Witten (incorporated by reference to exhibit 10.4(e) of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 16, 2005).
- 10.4(f) Assignment Agreement dated November 7, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Mark Witten (incorporated by reference to exhibit 10.4(f) of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).
- 10.4(g) Assignment Agreement dated November 7, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Mark Witten (incorporated by reference to exhibit 10.4(g) of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 16, 2005).
- 10.4(h) Assignment Agreement dated November 7, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Mark Witten (incorporated by reference to exhibit 10.4(h) of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 16, 2005).
- 10.5 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).

60

EXHIBIT NUMBER	DESCRIPTION OF EXHIBIT
-----	-----
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

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

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

- 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).
- 10.10 Employment Agreement dated February 15, 2005 between the Registrant and John N. Fermanis (incorporated by reference to exhibit 10.10 of the Registrant's Amendment No. 1 on Form 10-K/A to its annual report for the year ended December 31, 2004).
- 10.11 Employment Agreement dated August 10, 2005 by and between the Registrant and Michael K. Wilhelm (incorporated by reference to exhibit 10.1 of the Registrant's quarterly report on Form 10-QSB for the three months ended September 30, 2005).
- 10.12 Change of Control Agreement dated August 10, 2005 by and between the Registrant and Michael K. Wilhelm (incorporated by reference to exhibit 10.2 of the Registrant's quarterly report on Form 10-QSB for the three months ended September 30, 2005).
- 10.13 Severance Agreement dated November 7, 2005 by and between the Registrant and Michael K. Wilhelm (incorporated by reference to exhibit 10.3 of the Registrant's quarterly report on Form 10-QSB for the three months ended September 30, 2005).
- 10.14 Authorization for Regulatory Contact dated November 7, 2005 between Immuneregen BioSciences, Inc., a subsidiary of the Registrant, and Synergos, Inc. (incorporated by reference to exhibit 10.14 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).
- 10.15 Proforma invoice/quotation dated November 7, 2005 from Sigma-Aldrich, Inc. to ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant (incorporated by reference to exhibit 10.15 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 16, 2005).

61

EXHIBIT NUMBER	DESCRIPTION OF EXHIBIT
10.16	Letter of acceptance dated October 2, 2003, from Huntingdon Life Sciences to ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant (incorporated by reference to exhibit 10.16 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).
10.17	Price Quotation dated June 27, 2003 received by ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant from AppTec

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

- Laboratory Services (incorporated by reference to exhibit 10.17 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).
- 10.18 Consulting Agreement dated March 15, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Dr. Hal Siegel, Ph.D. (Siegel Consultancy) (incorporated by reference to exhibit 10.18 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).
- 10.19 Consulting Agreement dated November 3, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Dr. Jack Caravelli, Ph.D (incorporated by reference to exhibit 10.19 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).
- 10.20 Consulting Agreement dated July 29, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Dr. Kelly McQueen, MD, MPH (incorporated by reference to exhibit 10.20 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on February 22, 2006).
- 21.1 Subsidiaries of Registrant (incorporated by reference to exhibit 21.1 of the Registrant's registration statement on Form SB-2 (File No. 333-120784) filed with the Securities and Exchange Commission on November 24, 2004).
- 23.1 Consent of Russell Bedford Stefanou Mirchandani LLP
- 31.1 Certification of Chief Executive Officer pursuant to Item 601(b)(31) of Regulation S-B, as adopted pursuant to Section 302  
of the Sarbanes-Oxley Act of 2002.
- 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

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

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.

62

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth fees billed to us by our auditors during the fiscal years ended December 31, 2005 and December 31, 2004 for: (i) services rendered for the audit of our annual financial statements and the review of our quarterly financial statements, (ii) services by our auditor that are reasonably related to the performance of the audit or review of our financial statements and that are not reported as Audit Fees, (iii) services rendered in connection with tax compliance, tax advice and tax planning, and (iv) all other fees for services rendered.

	December 31, 2005	December 31, 2004
(i) Audit Fees	\$67,000	\$75,341
(ii) Audit Related Fees	--	--
(iii) Tax Fees	10,000	--
(iv) All Other Fees	--	--
Total fees	\$77,000	\$75,341

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

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

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

63

#### 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 March 28, 2006

IR BIOSCIENCES HOLDINGS, INC.

Edgar Filing: IR BIOSCIENCES HOLDINGS INC - Form 10KSB

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)	March 28, 2006
/s/ John N. Fermanis ----- John N. Fermanis	Chief Financial Officer (Principal Financial and Accounting Officer)	March 28, 2006
/s/ Theodore E. Staahl ----- Theodore E. Staahl, M.D.	Director	March 28, 2006