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IR BIOSCIENCES HOLDINGS INC

Form SB-2/A

February 22, 2006

AS FILED WITH THE SECURITIES AND  
EXCHANGE COMMISSION ON FEBRUARY 22, 2006 REGISTRATION NO. 333-120784

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

FORM SB-2/A  
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933  
(AMENDMENT NO. 3)

IR BIOSCIENCES HOLDINGS, INC.  
(NAME OF SMALL BUSINESS ISSUER IN ITS CHARTER)

DELAWARE	2834	13-3301899
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)	(PRIMARY STANDARD INDUSTRIAL CLASSIFICATION CODE NUMBER)	(I.R.S. EMPLOYER IDENTIFICATION NO.)

4021 NORTH 75TH STREET, SUITE 201  
SCOTTSDALE, ARIZONA 85251  
(480) 922-3926  
(ADDRESS AND TELEPHONE NUMBER OF PRINCIPAL EXECUTIVE OFFICES)

MICHAEL K. WILHELM, CHIEF EXECUTIVE OFFICER  
4021 NORTH 75TH STREET, SUITE 201  
SCOTTSDALE, ARIZONA 85251  
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(NAME, ADDRESS AND TELEPHONE NUMBER OF AGENT FOR SERVICE)

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APPROXIMATE DATE OF PROPOSED SALE TO THE PUBLIC: From time to time after the  
effective date of this Registration Statement

If any of the securities being registered on this form are to be offered on  
a delayed or continuous basis pursuant to Rule 415 under the Securities Act of  
1933, check the following box.

If this form is filed to register additional securities for an offering  
pursuant to Rule 462(b) under the Securities Act, check the following box and  
list the Securities Act registration statement number of the earlier effective  
registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c)  
under the Securities Act, check the following box and list the Securities Act

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registration statement number of the earlier effective registration statement for the same offering. |\_|

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement the same offering. |\_|

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. |\_|

CALCULATION OF REGISTRATION FEE			
TITLE OF EACH CLASS OF SECURITIES TO BE REGISTERED	AMOUNT TO BE REGISTERED (1)	PROPOSED MAXIMUM OFFERING PRICE PER SHARE	PRO AGGR
Common stock, \$.001 par value (6)	33,075,843	\$0.18 (2)	\$ 5,
Common stock, \$.001 par value (7)	10,019,600	0.18 (2)	1,
Common stock, \$.001 par value (6)	5,192,135	0.31 (3)	1,
Common stock, \$.001 par value (7)	5,432,891	0.31 (3)	1,
Common stock, \$.001 par value (6)	2,545,140	0.50 (4)	1,
Common stock, \$.001 par value (6)	1,928,400	0.23 (5)	
	=====		
Total Registration Fee			

(Footnotes to table on next page)

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL HEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF THE SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SUCH SECTION 8(A), MAY DETERMINE.

- (1) In accordance with Rule 416(a), the Registrant is also registering hereunder an indeterminate number of additional shares of common stock that shall be issuable pursuant to Rule 416 to prevent dilution resulting from stock splits, stock dividends or similar transactions.
- (2) Estimated pursuant to Rule 457(c) of the Securities Act of 1933 solely for the purpose of computing the amount of the registration fee based on the average of the bid and ask prices reported on the OTC Bulletin Board on November 22, 2004.
- (3) Estimated pursuant to Rule 457(c) of the Securities Act of 1933 solely for the purpose of computing the amount of the registration fee based on the average of the bid and ask prices reported on the OTC Bulletin Board on July 19, 2005.
- (4) Estimated pursuant to Rule 457(c) of the Securities Act of 1933 solely for

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the purpose of computing the amount of the registration fee based on the average of the bid and ask prices reported on the OTC Bulletin Board on November 11, 2005.

- (5) Estimated pursuant to Rule 457(c) of the Securities Act of 1933 solely for the purpose of computing the amount of the registration fee based on the average of the bid and ask prices reported on the OTC Bulletin Board on February 16, 2006.
- (6) Represents shares of the Registrant's common stock being registered for resale that have been issued to the selling stockholders named in the prospectus or a prospectus supplement.
- (7) Represents shares of the Registrant's common stock being registered for resale that have been or may be acquired upon the exercise of warrants issued to the selling stockholders named in the prospectus or a prospectus supplement.
- (8) Previously paid.

PROSPECTUS

Subject to Completion, Dated February 22, 2006

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

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58,194,009 SHARES

IR BIOSCIENCES HOLDINGS, INC.

COMMON STOCK

This prospectus relates to 58,194,009 shares of common stock of IR BioSciences Holdings, Inc. that may be sold from time to time by the selling stockholders named in this prospectus. We will not receive any proceeds from the sales by the selling stockholders, but we will receive funds from the exercise of warrants held by selling stockholders, if exercised.

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Our common stock is traded on the OTC Bulletin Board maintained by the National Association of Securities Dealers, Inc. under the symbol "IRBO." On February 16, 2006, the closing sales price for our common stock on the OTC Bulletin Board was \$0.23 per share.

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THE SECURITIES OFFERED BY THIS PROSPECTUS INVOLVE A HIGH DEGREE OF RISK. SEE "RISK FACTORS" BEGINNING ON PAGE 6.

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Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

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The date of this prospectus is February 22, 2006

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## PROSPECTUS SUMMARY

This summary highlights some information from this prospectus, and it may not contain all of the information that is important to you. You should read the following summary together with the more detailed information regarding our company and the common stock being sold in this offering, including "Risk Factors" and our consolidated financial statements and related notes, included elsewhere in this prospectus. All share and per share information included in this prospectus has been adjusted for a 1-for-20 reverse split of our common stock that we effected in July 2003 and a 2-for-1 forward stock split of our common stock that we effected in April 2004.

## OUR COMPANY

### GENERAL

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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 (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 Homspira 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 Homspira 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 Homspira. Radilex(TM) is being formulated specifically for the treatment of acute exposure to radiation. Viprovex(TM) is being formulated specifically for 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 a mouse radiation study 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 are designing 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 Homspira (now Radilex) in the treatment of acute 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 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 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 Homspira, 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 Homspira 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 Homspira. Even if human testing is permitted, none of Radilex, Viprovex or any other potential drug candidates, if any, derived from Homspira may be successfully developed or shown to be safe or effective.

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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 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.

### 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 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 DEVELOPMENTS

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.

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.

During nine months ended September 30, 2005, our Board of Directors

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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. On August 23, 2005, trademarks for Radilex and Viprovex were approved and passed to publication by the USPTO. The publication date for these two trademarks was September 6, 2005.

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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 of our common stock. In consideration of the investment, we granted to each investor certain registration rights and anti-dilution rights.

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

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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.

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.

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### THE OFFERING

Common stock offered by  
selling stockholders.....58,194,009 shares(1)  
Common stock outstanding.....69,231,182 shares(2)  
Use of proceeds.....We will not receive any proceeds from the  
sale of the common stock, but we will  
receive funds from the exercise of warrants  
by selling stockholders, if exercised.

OTC Bulletin Board..... IRBO  
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- (1) Represents 48,362,696 shares of our common stock that were issued to selling stockholders and 9,831,313 shares of our common stock underlying warrants that were issued to selling stockholders.
- (2) The number of shares of common stock outstanding as of December 31, 2005 listed above excludes:
  - o 63,212 shares of our common stock issuable upon exercise of options at a weighted average exercise price of \$25.00 per share that were granted outside of our 2003 Stock Option, Deferred Stock and Restricted Stock Plan;
  - o 150,000 five-year common stock purchase options at an exercise price of \$0.44 granted under our 2003 Stock Option, Deferred Stock and Restricted Stock Plan;



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- o 103,030 five-year common stock purchase options at an exercise price of \$0.33 granted under our 2003 Stock Option, Deferred Stock and Restricted Stock Plan;
- o 11,675,469 shares of our common stock issuable upon exercise of warrants with exercise prices ranging from \$0.01 to \$2.00 per share; and
- o 455,441 shares of common stock that have been committed due to convertible features of notes, employment and advisory agreements that are not yet issued.

The total number of shares of common stock offered for resale by the selling stockholders listed in this prospectus includes 5,534,400 shares of issued and outstanding common stock and 2,179,200 shares of common stock issuable upon the exercise of five-year warrants with an exercise price of \$0.50 issued in connection with a penalty clause regarding the registration of shares sold in our private placement in October 2004. For each 30-day period beyond 90-days following the second closing date (October 26, 2004), we have agreed to issue to the holders of units sold in the private placement an additional 2% a month, or in aggregate 461,200 shares and 181,600 warrants until such a time as this Registration Statement is declared effective by the Securities and Exchange Commission. We have committed these shares although they remain unissued.

### SUMMARY FINANCIAL INFORMATION

The following summary financial information has been derived from the financial statements that are included elsewhere in this prospectus. You should read this information in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and the related notes thereto included elsewhere in this prospectus.

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	For the Three Months Ended Sept 30, 2005	For the Three Months Ended Sept 30, 2004	For the Nine Months Ended Sept 30, 2005	For t Month Sep 2
	-----	-----	-----	-----
Revenues	--	--	--	
Operating expenses:				
Selling, general and				
administrative expenses	\$ 507,445	\$ 1,041,152	\$ 1,939,800	\$ 3,
Merger fees and costs	--	--	--	
Financing cost	579,575	--	2,072,831	
	-----	-----	-----	-----
Total operating expenses	1,087,020	1,041,152	4,012,631	3,
Operating loss	(1,087,020)	(1,041,152)	(4,012,631)	(3,
Other expense:				
Interest income (expense)	5,925	(70,612)	4,607	(
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Total other expense	5,925	(70,612)	4,607	
Loss before income taxes	(1,081,095)	(1,111,764)	(4,008,024)	(4,
Provision for income taxes	--	--	--	
Net loss	\$ (1,081,095)	\$ (1,111,764)	\$ (4,008,024)	\$ (4,
Net loss per share - basic and diluted	\$ (0.02)	\$ (0.04)	\$ (0.06)	\$
Weighted average shares outstanding - basic and diluted	69,337,210	29,040,133	67,103,634	27,

### ADDITIONAL INFORMATION

We are incorporated in State of Delaware. Our executive offices are located at 4021 N. 75th Street, Suite 201, Scottsdale, Arizona 85251. Our telephone number is (480) 922-3926. 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.

In this prospectus, the terms "we," "us," the "Company," and "our" refer to IR BioSciences Holdings, Inc., a Delaware corporation, and its consolidated subsidiary, as appropriate in the context, and, unless the context otherwise requires, "common stock" refers to the common stock, par value \$0.001 per share, of IR BioSciences Holdings, Inc.

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### RISK FACTORS

Any investment in our common stock involves a high degree of risk. You should carefully consider the risks described below and all of the information contained in this prospectus before deciding whether to purchase our common stock. The risks described below are all of the material risks that are facing our company. If any of the following risks actually occur, our business, financial condition and results of operations could be harmed. The trading price of our common stock could decline, and you may lose all or part of your investment in our common stock.

#### 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 September 30, 2005, we had a working capital deficit of \$1,725,791. This amount consists of cash of \$667,041 and current assets of \$15,713, accounts payable of \$170,909, accrued current liabilities of \$164,805 and an accrued current liability of \$2,072,831 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

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September 30, 2005, we would have working capital of \$347,040. We have incurred a substantial net loss for the period from our inception in October 2002 to September 30, 2005, and are currently experiencing negative cash flow. We expect to continue to experience negative cash flow and operating losses through at least 2008 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 nine months ended September 30, 2005 and for fiscal year 2004 was \$4,008,024 and \$5,305,407, respectively. As of September 30, 2005, we had an accumulated deficit of \$11,216,051.

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

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sufficient to fund our capital expenditures, working capital and other cash requirements beyond March 2006. Our working capital as of September 30, 2005 was \$347,040 net of the accrual of securities pursuant to the penalty 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

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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, 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 as 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.

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### RISKS RELATED TO OUR BUSINESS

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

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

- o ensure that 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;
- 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 around Radilex and Viprovex, which are potential drug candidates derived from Homspera. 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

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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 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.

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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 Homspira. 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 Homspira 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 Homspira 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 Homspira. Even if large animal or human testing is permitted, none of Radilex, Viprovex or any other potential drug candidate, if any, derived from Homspira 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.

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

THE MARKET FOR TREATING 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 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. While we have filed a formal response to the U.S. Department of Health and Human Services Request for Information (RFI) for therapeutics to treat ARS, at least one other company has responded to this RFI, and we cannot guarantee that our response to this RFI will result in a U.S. Department of Health and Human Services Request for Proposal (RFP) or any stockpiling orders. 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.

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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

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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;
- 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 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 Homospora 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

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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



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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 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 Homospora, 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.

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

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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:

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

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

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

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

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 Homspera 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

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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.

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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 timely and competitive basis.

For the manufacture of Radilex, Viprovex and Homspira, 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 Homspira are readily available from various sources, and several suppliers are capable of supplying substance P in both clinical and commercial quantities, our dependence on such manufacturers, may delay or impair our ability to generate revenues, or adversely affect our profitability.

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

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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 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.

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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 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.

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Legal standards relating to the validity of patents covering pharmaceutical and biotechnology inventions and the scope of claims made under such patents are still developing. In some of the countries in which we intend to market our products, pharmaceuticals are either not patentable or have only recently become patentable. Past enforcement of intellectual property rights in many of these countries has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries may be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions. The U.S. Patent and Trademark Office, commonly referred to as the USPTO, and the courts have not consistently treated the breadth of claims allowed in biotechnology patents. If the USPTO or the courts begin to allow broader claims, the incidence and cost of patent interference proceedings and the risk of infringement litigation will likely increase. On the other hand, if the USPTO or the courts begin to allow narrower claims, the value of our proprietary rights may be limited. Any changes in, or unexpected interpretations of the patent laws may adversely affect our ability to enforce our patent position.

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

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

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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

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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.

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 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 service would be detrimental to us and could

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have a material adverse effect on our business, financial condition and results of operations.

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

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

### RISKS RELATED TO THIS OFFERING

A LIMITED PRIOR PUBLIC MARKET AND TRADING MARKET MAY CAUSE VOLATILITY IN THE PRICE OF OUR COMMON STOCK AND THUS ADVERSELY AFFECT THE VALUE OF YOUR INVESTMENT.

Our common stock is currently traded on a limited basis on the OTC Bulletin Board (the "OTCBB") under the symbol "IRBO". The OTCBB is an inter-dealer, Over-The-Counter market that provides significantly less liquidity than the NASDAQ Stock Market. Quotes for stocks included on the OTCBB are not listed in the financial sections of newspapers as are those for the NASDAQ Stock Market. Therefore, prices for securities traded solely on the OTCBB may be difficult to obtain and holders of common stock may be unable to resell their securities at or near their original offering price or at any price.

The NASD has enacted recent changes that limit quotations on the 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 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

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the SEC in the 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.

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

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



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we failed to complete the registration. Through January 19, 2006, we have accrued 5,534,400 shares and 2,179,200 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 prospectus supplement, our authorized capital consists of 100,000,000 shares of common stock. As of February 16, 2006, we have 89,391,934 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.

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 15-2 through 15g-9 promulgated under the Exchange Act. For example, Rule 15g-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 15g-9 requires broker-dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any penny stock to that investor. This procedure requires the broker-dealer to (i) obtain from the investor information concerning his or her financial situation, investment experience and investment objectives; (ii) reasonably determine, based on that

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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.

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### NOTE REGARDING THIS PROSPECTUS

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Please read this prospectus carefully. It describes our business, our financial condition and results of operations. We have prepared this prospectus so that you will have the information necessary to make an informed investment decision.

You should rely on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. The selling stockholders are offering to sell shares of our common stock and seeking offers to buy shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of the prospectus, regardless of the time the prospectus is delivered or the common stock is sold.

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

In addition to historical information, this prospectus contains statements relating to our future business and/or results, including, without limitation, the statements under the captions "Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." These statements include certain projections and business trends that are "forward-looking" within the meaning of the United States Private Securities Litigation Reform Act of 1995 (the "PSLRA"). The safe harbor for forward-looking statements under the PSLRA does not apply to our company. You can identify these statements by the use of words like "may," "could," "should," "project," "believe," "anticipate," "expect," "plan," "estimate," "forecast," "potential," "intend," "continue" and variations of these words or comparable words. Forward-looking statements do not guarantee future performance and involve risks and uncertainties. Actual results will differ, and may differ materially, from projected results as a result of certain risks and uncertainties. These risks and uncertainties include, without limitation, those described under "Risk Factors" and those detailed from time to time in our filings with the SEC, and include, among others, the following:

- o Our ability to raise additional funding and the amounts raised, if any;
- o Our ability to successfully develop and commercialize any other proposed products, if any, derived from Homspera;
- o A lengthy approval process and the uncertainty of FDA and other government regulatory requirements may have a material adverse effect on our ability to commercialize Radilex, Viprovex or any other proposed product, if any, derived from Homspera;
- o Clinical trials may fail to demonstrate the safety and effectiveness of Radilex, Viprovex or any other proposed product, if any, derived from Homspera, which could have a material adverse effect on our ability to obtain government regulatory approval;
- o The degree and nature of our competition;
- o Our ability to employ and retain qualified employees; and
- o The other factors referenced in this prospectus, including, without limitation, under the sections entitled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Business."

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Other sections of this prospectus may include additional factors which could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or to the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, investors should not place undue reliance on forward-looking statements as a prediction of actual results. These forward-looking statements are made only as of the date of this prospectus. 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 prospectus.

### USE OF PROCEEDS

We will not receive any proceeds from the sale of the shares of common stock by the selling stockholders, but we will receive funds from the exercise of warrants held by selling stockholders, if exercised.

### MARKET FOR 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 February 16, 2006) \$	0.34	\$ 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	\$ 0.28
2nd Quarter	0.60	0.11
3rd Quarter	0.23	0.09
4th Quarter	0.50	0.15

On February 16, 2006, the closing price of our common stock as reported

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by the OTC Bulletin Board was \$0.23 per share. There were approximately 520 shareholders of record and beneficial stockholders of our common stock as of February 16, 2006. We have not paid any dividends on our common stock since inception and do not intend to do so in the foreseeable future.

### DIVIDEND POLICY

We have not declared or paid any cash dividends on our common stock, and we currently intend to retain future earnings, if any, to finance the expansion of our business, and we do not expect to pay any cash dividends in

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the foreseeable future. The decision whether to pay cash dividends on our common stock will be made by our board of directors, in their discretion, and will depend on our financial condition, operating results, capital requirements and other factors that the board of directors considers significant. We have never declared or paid any dividends on our securities. We currently intend to retain our earnings for funding growth and, therefore, do not expect to pay any dividends in the foreseeable future.

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

This prospectus 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 prospectus. 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 prospectus 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 prospectus.

### OVERVIEW

We were originally incorporated in State of Delaware in June 1985 under

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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 therapeutics in development are based on Sar9, Met (O2)11-Substance

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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(TM) is being formulated specifically for the treatment of acute exposure to radiation. Viprovex(TM) is being formulated specifically for 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 a mouse radiation study 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

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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

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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

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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 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 purchase any quantities of Radilex or Viprovex.

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.

### PRODUCT RESEARCH AND DEVELOPMENT

We incurred an expense of \$83,020 for the three months ended September 30, 2005 in research and development activities related to the development of Radilex and Viprovex versus an expense of \$22,709 for the three months ended September 30, 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 \$301,123 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 Harris, 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 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

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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 will need to generate significant revenues from product sales and or related royalties and license agreements to achieve and maintain profitability. Through September 30, 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

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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 technologies.

Our major research and development projects include:

Research and Development of Radilex in Radiological Exposure Applications.

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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. We are currently sponsoring an ongoing radiation study at the University of Arizona.

We have 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 further validate our prior studies. We expect to begin the study within the next 30 days. We estimate that the study will be completed within 3 months upon commencement 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 an additional \$3,500,000 will be required to complete this study. We estimate the completion of this study will be in 18 to 24 months.

We intend to apply for approval for the use of Radilex for the treatment of acute radiation syndrome 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



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trials and receive FDA 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 is granted, we expect to begin efforts to commercialize our product immediately thereafter. If approved, we are anticipating revenues from the sale of Radilex beginning in calendar year 2009.

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 Viprovex in Chemical and Biological  
Exposure Applications.

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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 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 is expected to begin in February, 2006. We estimate that the study will be completed within 3 months upon commencement at an estimated cost of \$51,450. If we are successful in achieving desirable results, we intend to design the protocols and begin studies for these indications, when capital is available. As we have only collected preliminary data and additional studies are required, we cannot predict when, if ever, a viable treatment can be commercialized. If we do not observe significant results or we lack

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the capital to further the development, we may abandon such research and development efforts; thereby limiting our future potential revenues.

### OFF-BALANCE SHEET ARRANGEMENTS

There were no off-balance sheet arrangements made in the fiscal quarter ended September 30, 2005.

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

### REVENUES

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

### COSTS AND EXPENSES

From our inception through September 30, 2005, we have incurred losses of \$11,216,051. These expenses were associated principally with equity-based

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compensation to employees and consultants, late registration penalty expenses, product development costs and professional services.

### LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2005, we had current assets of \$682,754 consisting of cash of \$667,041 and other current assets of \$15,713. At September 30, 2005, we also had current liabilities of \$2,408,545, consisting of accounts payable and accrued liabilities of \$335,714 and accrued penalties for late registration of \$2,072,831. This resulted in net working deficit at September 30, 2005 of \$1,725,791. During the nine months ended September 30, 2005, we used cash in operating activities of (\$1,482,933). From the date of inception (October 30, 2002) to September 30, 2005, we have had a net loss of (\$11,216,051) and have used cash of (\$3,557,278) in operating activities.

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 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 September 30, 2005 via the private placement of \$3,263,903 net of costs of our common stock, \$1,194,857 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 \$1,190,857 from the tender offer, net of costs.

During the nine months ended September 30, 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.

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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 \$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, and will continue to pay, through the term of Mr. Wilhelm's employment, an annual salary of \$250,000. Mr. Wilhelm's salary is payable in regular installments in accordance with the customary payroll practices of our company.

Pursuant to our employment agreement with John Fermanis, our Chief Financial Officer, dated February 15, 2005, we paid a salary of \$60,000 until the company completed a financing of \$500,000 or more. This occurred on March 4, 2005 when the company completed a Tender Offer for warrants totaling \$1,190,857 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 our company.

On December 16, 2002 we entered into a consulting agreement on a month-to-month basis with Dr. Mark Witten, our chief research scientist and 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.

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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

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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.

### Acquisition or Disposition of Plant and Equipment

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We did not dispose or acquire any significant property, plant or equipment during the nine months ended September 30, 2005.

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

### Number of Employees

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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.

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### 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

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

We elected to continue to account for stock-based compensation plans using the intrinsic value-based method of accounting prescribed by APB No. 25, "Accounting for Stock Issued to Employees," and related interpretations. Under the provisions of APB No. 25, compensation expense is measured at the grant date for the difference between the fair value of the stock and the exercise price. From its inception, the Company has incurred significant costs in connection with the issuance of equity-based compensation, which is comprised primarily of our

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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

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In November 2004, the Financial Accounting Standards Board (FASB)

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

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

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

On December 16, 2004, FASB issued Statement of Financial Accounting Standards No. 153, Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29, Accounting for Nonmonetary Transactions ("SFAS 153"). This statement amends APB Opinion 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. Under SFAS 153, if a nonmonetary exchange of similar productive assets meets a commercial-substance criterion and fair value is determinable, the transaction must be accounted for at fair value resulting in recognition of any gain or loss. SFAS 153 is effective for nonmonetary transactions in fiscal periods that

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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.

RESULTS OF OPERATIONS FOR THE THREE AND NINE MONTH PERIODS ENDED SEPTEMBER 30, 2005 AND FOR THE PERIOD OF INCEPTION (OCTOBER 30, 2002) TO SEPTEMBER 30, 2005.

Results of Operations for the Three Month Period Ended September 30, 2005 and 2004.

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Revenue  
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We are in the development stage and have no revenue.

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Sales, General, and Administrative Expenses  
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Sales, general, and administrative expenses ("SG&A") were \$507,445 for the three months ended September 30, 2005, a decrease of \$533,707 or approximately 51% compared to SG&A of \$1,041,152 during the three months ended September 30, 2004. The decrease is primarily due to lower costs of non-cash compensation. For the three months ended September 30, 2005, this amount consisted primarily of officer compensation of \$95,846, research and development of \$83,020, legal and accounting fees of \$79,085, other consulting fees of \$73,621, payroll and related costs of \$55,355, public relations and marketing of \$30,164, and non-cash compensation costs of \$23,586.

The Company expects SG&A to increase during the coming twelve months as we continue to utilize non-cash compensation in order to conserve cash, build out the Company's infrastructure, and continue to develop the Company's line of potential products.

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Penalties for Late Registration  
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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. During the three months ended September 30, 2005, we incurred additional penalties in the amount of \$579,575. As of September 30, 2005, we are required to issue additional 3,827,960 shares of common stock and warrants to purchase an additional 1,507,280 shares of common stock. These shares have been valued at the market price of the common stock at the time each 30 day period, for a total of \$1,539,331 at September 30, 2005; the warrants have been valued at \$533,500 at September 30, 2005 utilizing the Black-Scholes valuation model. The total value of the common stock and warrants issuable pursuant to this late filing penalty at September 30, 2005 is \$2,072,831. This amount was charged to finance cost during the nine months ended September 30, 2005 and is included in our balance sheet at September 30, 2005 as accrued penalty for late registration of

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shares.

We anticipate completing the registration of these shares during the quarter ended June 30, 2006, but expect that an obligation to issue approximately 1,844,800 additional shares and 726,400 additional warrants at an aggregate cost of approximately \$830,000 will be incurred.

### Interest Income/expense

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Interest income (net) for the three months ended September 30, 2005 was \$5,925, a decrease of \$76,537 compared to interest expense (net) of \$70,612 for the three months ended September 30, 2004. The decrease is due to a higher cash balances and a decrease in debt.

### Net Loss

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For the reasons above, primarily lower SG&A expenses and lower interest expenses offset by the late

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registration penalty, the net loss for the three months ended September 30, 2005 was \$1,081,095, an decrease of \$30,669 or approximately 3% compared to a net loss of \$1,111,764 for the three months ended September 30, 2004.

We expect losses to increase during the coming twelve months. We do not expect to begin to generate revenue in the coming twelve months, and our costs are likely to increase as we move our line of potential products through the testing and approval phases, and as we build out our corporate infrastructure.

Results of Operations for the Nine Month Period Ended September 30, 2005 and 2004.

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### Revenue

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We are in the development stage and have no revenue.

### Selling, General and Administrative Expenses

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Selling, general and administrative expenses were \$1,939,800 for the nine months ended September 30, 2005 which is a decrease of \$1,606,841 or approximately 45% compared to SG&A of \$3,546,641 for the nine months ended September 30, 2004. The decrease is primarily due to lower costs of non-cash compensation. This expense is primarily comprised of non-cash compensation of \$460,364, legal and accounting fees of \$408,109, consulting fees of \$268,598, officer compensation of \$212,838, payroll and related costs of \$149,809, research and development of \$108,439, public relation and marketing of \$95,047, travel and entertainment of \$82,546, and rent of \$23,043.

### Penalties for Late Registration

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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. During the three months ended September 30, 2005, we incurred additional penalties in the amount of \$579,575. As of September 30, 2005, we are required to issue additional 3,827,960 shares of common stock and warrants to purchase an additional 1,507,280 shares of common stock. These shares have been valued at the market price of the common stock at the time each 30 day period, for a total of \$1,539,331 at September 30, 2005; the warrants have been valued at \$533,500 at September 30, 2005 utilizing the Black-Scholes valuation model. The total value of the common stock and warrants issuable pursuant to this late filing penalty at September 30, 2005 is \$2,072,831. This amount was charged to finance cost during the nine months ended September 30, 2005 and is included in our balance sheet at September 30, 2005 as accrued penalty for late registration of shares.

We anticipate completing the registration of these shares during the quarter ended June 30, 2006, but expect that an obligation to issue approximately 1,844,800 additional shares and 726,400 additional warrants at an aggregate cost of approximately \$830,000 will be incurred.

### Interest Expense (Net)

Interest income (net) was \$4,607 for the nine months ended September 30, 2005, a decrease of \$511,034 compared to interest expense of \$506,427 for the nine months ended September 30, 2004. The decrease is due to a decrease in debt along with an increase cash balances.

### Net Loss

For the reasons above, primarily lower SG&A expenses and lower interest expenses offset by the late registration penalty, the net loss for the nine months ended September 30, 2005 was \$4,008,024, a decrease of \$45,044 or approximately 1% compared to a net loss of \$4,053,068 for the nine months ended September 30, 2004.

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RESULTS OF OPERATIONS FROM THE PERIOD OF INCEPTION (OCTOBER 30, 2002) TO SEPTEMBER 30, 2005.

### SELLING, GENERAL, AND ADMINISTRATIVE EXPENSES

SG&A expenses were \$7,529,684 from the period of inception (October 30, 2002) to September 30, 2005.

### FINANCING COST

Financing costs were \$2,162,831 from the period of inception (October 30, 2002) to September 30, 2005.

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### INTEREST EXPENSE

Interest expense was \$1,173,536 from the period of inception (October 30, 2002) to September 30, 2005.

### NET LOSS

Our net loss was \$11,216,051 from the period of inception (October 30, 2002) to September 30, 2005.

RESULTS OF OPERATIONS FOR THE TWELVE MONTH PERIOD ENDED DECEMBER 31, 2004 AND FOR THE PERIOD OF INCEPTION (OCTOBER 30, 2002) TO DECEMBER 31, 2004.

### REVENUE

We are currently in the development stage and have not yet generated any revenue.

### SELLING, GENERAL, AND ADMINISTRATIVE EXPENSES

SG&A expenses were \$4,498,390 for the twelve months ended December 31, 2004. These expenses are primarily comprised of non-cash compensation of \$3,284,577, legal and accounting fees of \$271,077, officer wages of \$175,000, research and development costs of \$150,091, consulting fees of \$169,311, and contract labor of \$89,989.

Total SG&A expenses for the period of inception (October 30, 2002) through December 31, 2004, were \$5,589,884. This increase of \$1,091,494 from the twelve months ended December 31, 2004 consists primarily of an additional \$125,000 in officer wages, an additional \$264,630 in legal and accounting fees, an additional \$204,354 in consulting fees, and an additional \$86,611 in non-cash compensation.

### MERGER FEES AND COSTS

Merger fees and costs were \$0 for the twelve months end December 31, 2004 and \$350,000 for the period of inception (October 30, 2002) to December 31, 2004. This amount is related to the reverse merger between GPN Network, Inc. and ImmuneRegen Biosciences, Inc., which was consummated in July 2003. \$185,000 of this amount were monies paid to the former controlling shareholder of GPN Network, Inc., and the remaining \$165,000 of these funds were used to satisfy certain outstanding liabilities of GPN Network, Inc.

During the twelve months ending December 31, 2005 we may investigate potential acquisition candidates, and the potential cash costs of such an acquisition or acquisitions is not possible to forecast.

### FINANCING COST

Financing costs were \$0 for the twelve months ending December 31, 2004 and \$90,000 for the period of inception (October 30, 2002) to December 31, 2004. This amount consists of non-refundable prepaid travel and road show costs relating to the reverse merger and an aborted private offering.

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### INTEREST EXPENSE

Interest expense during the twelve months ended December 31, 2004 was

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\$807,017. This amount consists of interest payable on our notes payable. An additional \$371,126 of interest was accrued during the period of inception (October 30, 2002) through December 31, 2003.

### NET LOSS

For the reasons stated above, our net loss for the twelve months ending December 31, 2004 was \$5,305,407 or \$0.16 per share. For the period of inception (October 30, 2002) through December 31, 2004, our net loss was \$7,208,027 or \$0.28 per share. We expect that losses will continue through the period ending December 31, 2005.

### 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 (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. The name Radilex(TM) has been trademarked for the formulation of Homspera specifically designated for the indication of acute exposure to radiation. Viprovex(TM) was trademarked specifically for the formulation of Homspera designated for applications relating to the potential treatment of maladies caused by the exposure to various chemical and biological agents. 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 are currently conducting pre-clinical studies in these areas.

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 developing. 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.

#### 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 the most potent member of the tachykinin family of neuropeptides, which are widely distributed in the

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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, Dr. Mark Witten and Dr. 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.

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### Radilex and Viprovex

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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 and Viprovex is the name of the anti-viral preparation for indications to potentially protect against exposure to various chemical and biological agents.

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-founder and Director, Dr. Mark Witten. During this research it was observed that the exposure of animals to jet fuel (JP-8) resulted in pathological changes in the lung and immune systems of those exposed. In the opinion of management, these studies further showed that

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the administration of Sar9, Met(02)11-Substance P prevented and reversed the effects of 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, that Homspira 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 (02)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, 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.

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

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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				
Chemical exposure					
Viprovox	In-progress				

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

To date we have been issued two Pre-Investigational New Drug (PIND)

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numbers by the U.S. Food & Drug Administration (FDA) - use of Homspera (now Radilex) in the treatment of acute radiation syndrome and use of Viprovex in the treatment of avian influenza. In addition, we have recently submitted a PIND for the use of Viprovex 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 protocol on a large animal study to test the efficacy of Radilex as a potential treatment for acute radiation syndrome. Also within the next six months, we expect to submit an Investigational New Drug (IND) application for the use of Viprovex in potentially treating Acute Respiratory Distress Syndrome (ARDS).

### RADILEX

To date we have sponsored three studies and co-sponsored five 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, these early rodent studies using Radilex have shown 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. Further, we believe that the use of an inhaler device may help simplify administration in such situations.

The results of these studies were presented to scientific members of Armed Forces Radiobiology Research Institute (AFRRI) on September 21, 2005. The data presented has moved AFRRI to request a collaboration with us to study Radilex in their facility and use their particular application and assessment parameters.

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

Prior to our formation, initial studies were conducted using Homspera (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

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doses were to be explored in subsequent studies.

- o Mouse radiation study number two was a pilot study sponsored by the AFOSR. This study was

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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 Homspera (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 Homspera treatment after 9 Gy radiation may have efficacy against acute radiation syndrome and that the radiation exposed, Homspera treated mice lived an average of two days longer than untreated, radiation exposed mice.

Our sponsored and co-sponsored studies completed to date, 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 Homspera 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 and administering a dose of 50mi, this study demonstrated that Homspera (now Radilex) treatment 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 Homspera (now 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 Homspera (now Radilex) efficacy 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, Homspera-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

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Homspera-treated, radiation-exposed mice showed no significant differences in their immune system.

- o Pilot mouse radiation study number 6, sponsored by ImmuneRegen, 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 Homspera 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 gray, 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.

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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. This study was intended to find a maximum efficacious dose of Homspera 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 subject's



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vulnerability to elements that would impact study results.

- o A blood profile study sponsored by us and conducted at the University of Arizona College of Medicine, Tucson, Arizona on August 25, 2005 was an exploratory pilot study to show 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, a radiation sensitivity animal model study using C57BL/6 mice at the University of Arizona College of Medicine, Tucson, Arizona was initiated. The study was sponsored by ImmuneRegen BioSciences, Inc. 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 March 2006.
- o We are finalizing the protocols for a small study to confirm the potential efficacy of Radilex in treating acute radiation syndrome. This study is expected to be conducted at Armed Forces Radiobiological Research Institute (AFRRI) facilities. The start date is to be determined as the proper equipment used to test Radilex needs to be located and installed at the AFRRI facility.
- o We have finalized the protocols for what we believe will be our final phase of rodent studies. We anticipate these studies to be conducted at Oak Ridge National Laboratory beginning in February 2006. These studies are designed to follow the AFRRI 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. Additionally, a wide range of dosage, as well as rodents with varying genetic backgrounds will likely be included, unlike previous studies. 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 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 (PIND No. 63,255) for the use of Homspera (now Radilex) 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 60 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.

#### VIPROVEX

We are also researching the efficacy of Viprovox 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 Viprovox (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.

To date, we have only conducted limited preclinical studies with regard to the development of Viprovox. In the opinion of management, preliminary results from pilot studies reveal the potential effects of Viprovox 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 Viprovox 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 Homspira (now Viprovox) under the direction of our co-founder, Director and research scientist, 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 Homspira (now Viprovox) 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 Viprovox directly stimulated the production of immune system cells which remained viable after Viprovox treatment.

Our pilot studies to date and current studies with regard to the development of Viprovox are summarized below.

- o In September 2003, a pilot study was conducted at the University of Arizona, Arizona Health Sciences Center, Lung Injury Laboratory using Viprovox 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 Viprovox 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 virus.
- o In October 2003 the AFOSR sponsored preliminary studies with

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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 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

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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 (Homspera) 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. The lungs were excised and sent to Georgetown University School of Medicine for further analysis.
- 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

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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 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 is expected to begin 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 (PIND No. 73,709) for the use of Viprovex in treating avian flu was issued on December 19, 2005. We are currently designing the protocols for additional studies to be utilized upon acceptance of competitive grants applied for from the Federal Defense Threat Reduction Agency. If we are successful in receiving this or additional grants for avian influenza, the study will be conducted with Battelle Laboratories in Columbus, Ohio as subcontractor at their Biolevel 3 facility. 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 months.

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Based on the results of our co-sponsored 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

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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 months.

We spent approximately \$150,091 and \$42,972 in 2004 and 2003, respectively, in research and development activities related to the development of Homspera, namely Radilex and Viprovex, as a protectant against the effects of biological and radiological agents. From our inception in October 2002, we have spent \$301,123 in research and development activities. Significant costs relating to research and development, such as consulting fees for Drs. Witten and Harris, 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 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 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 for the use of 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 for such an indication 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

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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)

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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 help 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 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.

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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 Homspira) 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

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(CBRN) attacks. We are led to this conclusion because in management's opinion the methods of action of Radilex do not simply 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. As of February 15, 2006, the awarding of the grants is still pending.

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

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(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 February 16, 2006, the awarding of the grants is still pending.

### Correspondence with FDA and NIH

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

On October 16, 2003, Jennifer L. Wike, of our Contract Research Organizations, or CRO, (Synergos, Inc.), spoke with Sandy Barnes, FDA Project Manager. Ms. Barnes asked whether our ARDS Pre-IND meeting package was ready to be sent to them and, also, that ---- she had put ImmuneRegen on their agenda for two potential dates (both in November 2003). Twelve copies of the meeting "information package" were requested be sent to her.

On October 30, 2003, Jennifer L. Wike, of our CRO (Synergos, Inc.), returned a call to Dr. Ray Anthracite, FDA Medical Reviewer. He had called with a question about the structure of Sar9, Met (O2)11-Substance P, more specifically "What amino acid did "Sar" refer?." After researching this, Ms. Wike called him to explain that "Sar" is sarcosine (N-methylglycine, an amino acid that occurs as an intermediate in the metabolism of choline in the kidney and liver. Dr. Anthracite confirmed that he is the medical reviewer for this product; he could not confirm the date for the Pre-IND teleconference, but did say that the agency had an internal meeting for the product set for November 5, 2003.

On November 4, 2003, Jaye Thompson, Ph.D., of our CRO (Synergos, Inc.), received a call from Cheryl Turner, FDA Division of Counterterrorism (DCT). Ms. Turner stated that the division wanted to have an introductory call with the company. 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 possibility of Sar9, Met (O2)11-Substance P in treating Acute Radiation Syndrome (ARS).

On November 4, 2003, Jennifer L. Wike, of our CRO (Synergos, Inc.), received a call from Sandy Barnes, FDA Project Manager to inform that the Pre-IND ARDS meeting was scheduled for November 18, 2003 and that we would receive written comments within a few days of their internal meeting on November 5th. They briefly discussed the scheduling of the ARS meeting which was set for November 17, 2003.

On November 17, 2003 a member of ImmuneRegen and regulatory consultants from Synergos, Inc. engaged in a teleconference with representatives from the FDA's Division of Counterterrorism (DCT) to discuss the

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development of Homspira for use in the event of a 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 meeting confirmation from Ryan



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Barraco, FDA Consumer Safety Officer via fax. This confirmed the 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 letter 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. The fax attached 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 the 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, members of the company and representatives of the FDA met 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 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 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 NIH contacted the company to let us know that Homspera's Mechanisms of Action were needed for a Request for Information (RFI) submission.

On November 1, 2004 the Mechanisms of Action for Homspera were sent electronically to Dr. Helen Quill of the NIH.

On December 28, 2004 the company received an email from Ms. Cheryl Turner of the FDA's Division of Counterterrorism. The email stated that if the company had not already forwarded an RFI specifically for Acute Radiation-Counterterrorism Indication that we should contact Dr. Helen Quill of the NIH and confirm that she had indeed received the necessary data from the company for the Counterterrorism Indication.

On January 11, 2005, we received a meeting confirmation from Ryan Barraco, FDA Consumer Safety Officer via fax. This confirmed the meeting date of February 17, 2005 at 11:30AM EST in Rockville, MD in relation to Pre-IND 63,255 for Radilex (Homspera). (Pre-IND CDER offers a Pre-Investigational New Drug Application (IND) Consultation Program to foster early communications between sponsors and new drug review divisions in order to provide guidance on the data necessary to warrant IND submission). The confirmation letter also stated that the agency required receipt of 18 hard copies and one disk of the company's background package no later than January 20, 2005.

On February 15, 2005 the company received via fax from Ryan Barraco, FDA Consumer Safety Officer the FDA responses to our questions posed in the background package dated January 28, 2005.

On February 22, 2005 representatives from the company met with members of the NIH. At this meeting several topics were discussed including the potential use of Viprovex in an anthrax model, conducting further studies conducted under an AFRRRI model using Radilex as a treatment for acute radiation syndrome, as well as additional pharmacokinetic and dose-timing.

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

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On September 6, 2005 Michael Wilhelm, CEO and Dr. Hal Siegel, Director of Product Development and Regulatory Affairs of the company met with Department of Homeland Security in Washington, DC. We met with Drs. Vitko and Pilai and discussed the company's compound and its efficacy. Also discussed was the company's 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 therapeutic.

On September 21, 2005 Michael Wilhelm, Dr. Hal Siegel and Dr. Mark Witten presented to Armed Forces Radiobiology Research Institute (AFRRI) at their offices in Bethesda, Maryland. The company presented their findings of possible efficacy in treating Acute Radiation Sickness with its drug Radilex. The company mentioned that it has always used survival as an end point to the lethal exposure studies and believes that best form of administration remains to be inhalation. AFRRI researchers confirmed that a study using the preexisting AFRRI rodent radiation model as a guide be completed.

On December 19, 2005 the company received a letter via US Mail from Department of Health and Human Services (DHHS) thanking us for our (Viprorex) 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.

On December 19, 2005 an email was received by the company from Dr. Mark H. Whitnall of AFRRI. The letter stated that they were intrigued by the company's countermeasure candidate Radilex presented to them at a meeting on November 21, 2005. Their organization now had funding mechanisms in place to test our molecule if the company wishes to proceed.

### COLLABORATORS AND CONTRACTORS

We have fostered and managed relationships with other laboratories 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 with currently include:

- o We have sponsored three mouse radiation studies at the University of Arizona College of Medicine, Tucson, Arizona since January, 2005 and are currently conducting a fourth 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 Homospora.
- 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

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of anthrax studies testing Viprovex as a treatment to anthrax infection. These studies are conducted by Hyperion 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 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.
- 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 (DTRA) in January, 2006 in response to their Broad Agency Announcement, Grant # DTRA01-06-BAA-01 for therapeutics against bio-terrorism.

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- o Oak Ridge National Laboratory (Oak Ridge, Tennessee). We have contracted with ORNL to conduct Proof of Concept mouse radiation studies to begin 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 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

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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 Advisory for the Treat 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

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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 Homspira 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

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

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

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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

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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

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

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

In the process of researching a deployment plan, 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 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

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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 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

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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

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pending Patent Cooperation Treaty (PCT) applications, seven pending U.S. applications and 16 pending foreign patent applications. The assignment documents are included as Exhibits.

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Registered Patents:

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Title -----	Serial No. -----
Substance P Treatment for Immunostimulation	US 5,945,508
Substance P Treatment for Immunostimulation	US 5,998,376
Substance P Treatment for Immunostimulation	Australia 737201
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 such funding, the U.S. Government has certain rights in the technology developed with the funding. 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.

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

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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 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

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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 Chief Scientific Officer and 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.

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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 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

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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

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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 FDCA and other Federal statutes and regulations govern or influence the research, 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 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 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

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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 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,

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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,

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in some circumstances, impose restrictions on the use of the product, which may be difficult and expensive to administer and may require prior approval of promotional materials.

### ONGOING FDA REQUIREMENTS

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

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

Manufacturers are also subject to various state and Federal laws and regulations governing laboratory practices (specifically, the requirement for certain studies to comply with current Good Laboratory Practices), the

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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

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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 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 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.

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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

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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.

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.

### FLUCTUATION OF QUARTERLY OPERATING RESULTS

Our quarterly operating results may fluctuate significantly in the future as a result of a variety of factors, many of which are outside our control. These factors include: the level of demand for Radilex, Homspera and any other products; our ability to attract and retain personnel with the necessary strategic, technical and creative skills required for effective operations; the amount and timing of expenditures by customers; the amount and timing of capital expenditures and other costs relating to the expansion of our operations; government regulation and legal developments regarding the use of Homspera; and general economic conditions. As a strategic response to changes in the competitive environment, we may from time to time make certain pricing, service, technology or marketing decisions that could have a material adverse effect on our quarterly results. Due to all of these factors, our operating results may fall below the expectations of securities analysts, stockholders and investors in any future quarter.

### PROPERTY

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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.

### 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 of \$28,091 has been accrued and is contained in the \$1,843,088 of Accounts Payable and Accrued Liabilities on the Company's condensed consolidated balance sheet of June 30, 2005.

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.

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### MANAGEMENT

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

Name	Age	Position
Michael K. Wilhelm	38	President, Chief Executive Officer and Director
John N. Fermanis	51	Chief Financial Officer
Mark L. Witten, Ph.D.	51	Director and Research Scientist
Theodore E. Staahl, M.D.	59	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

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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.

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 average 3 hours per week to our business.

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. Additionally, Dr. Staahl is currently participating in the FDA approval process of another biotechnology company. Dr. Staahl devotes on average 3 hours per week to our business.

### COMPENSATION OF DIRECTORS

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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.

On December 16, 2002 we entered into a consulting agreement with 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

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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.

### COMMITTEES AND ATTENDANCE AT BOARD MEETINGS

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.

### EXECUTIVE COMPENSATION

The following table sets forth information concerning all compensation awarded to, earned by, or paid to (1) our Chief Executive Officer and President, (2) our former Chief Executive Officer and President who served in such capacities until July 2003 when ImmuneRegen BioSciences, Inc. became a wholly-owned subsidiary of IR BioSciences, Inc. (the "Reorganization") and (3) each of the other executive officers whose annual salary and bonus during 2002, 2003 and 2004 exceeded \$100,000 (the "Named Executive Officers").

NAME AND PRINCIPAL POSITION	YEAR	ANNUAL COMPENSATION SALARY (\$)
	2004	175,000
Michael K. Wilhelm	2003	125,000
Chief Executive Officer and President (1) .....	2002	5,208
Todd M. Ficeto	2004	0
Chief Executive Officer, Chief Financial Officer,	2003	0
President and Secretary (3) .....	2002	0

(1) Michael K. Wilhelm has served as Chief Executive Officer and President of IR BioSciences Holdings, Inc. since July 2003 when the Reorganization was completed. Prior to the completion of the Reorganization, Mr. Wilhelm served as Chief Executive Officer and President of ImmuneRegen BioSciences, Inc. since December 2002. Mr. Wilhelm's compensation is reported in the table with respect to his positions at both IR BioSciences Holdings, Inc. and ImmuneRegen BioSciences, Inc. for the years ended December 31, 2003 and 2004.

(2) 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

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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.

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

### 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

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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 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.

On February 15, 2005, we entered into an employment agreement with our 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

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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.

### OPTION/SAR GRANTS IN LAST FISCAL YEAR

We did not grant stock options to any of the Named Executive Officers during the year ended December 31, 2004.

### AGGREGATE OPTION EXERCISED IN FISCAL 2004 AND FISCAL YEAR-END OPTION VALUES

None of the Named Executive Officers exercised any stock options during the year ended December 31, 2004. As of June 30, 2005 only Michael Wilhelm, the Chief Executive Officer, held stock options.

### STOCK OPTIONS

We issued 150,000 stock options to our Chief Executive Officer, Michael Wilhelm, during the nine month period ended September 30, 2005. We did not issue options to any of our employees during the years ended December 31, 2003 and 2004.

Subject to the separate approvals by the Board, a one time grant of an incentive option to our Chief Executive Officer to purchase 103,030 shares of the Company's common stock, at an exercise price equal to 110% of the fair

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market value per share on the date the option is granted and a nonstatutory option to purchase 1,896,970 shares at the fair market value per share on the date the option is granted such time that the Company's 2003 Stock Plan is amended to authorize additional shares.

### 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. During nine months ended September 30, 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. Subject to the separate approvals by the Board, a one time grant of an incentive option to our Chief Executive Officer to purchase 103,030 shares of the Company's Common Stock, at an exercise price equal to 110% of the fair market value per share on the date the option is granted and a nonstatutory option to purchase 1,896,970 shares at the fair market value per share on the date the option is granted such time that the Company's 2003 Stock Plan is amended to authorize additional shares.

We 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.

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### SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

The following table provides information as of December 31, 2004 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	Weighted- average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders.....	0 (1)	N/A	445,996 (3)



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Equity compensation plans not approved by security holders.....	17,729,422 (2)	\$0.49	--
Total.....	17,729,42		445,996
	=====		=====

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- (1) Represents stock options outstanding under our 2003 Stock Option, Deferred Stock and Restricted Stock Plan.
  - (2) Represents 17,666,210 stock purchase warrants at a weighted average price of \$0.49 and 63,212, options at a weighted average exercise price of \$20.00.
  - (3) Represents 445,996 shares are available for future issuance under our 2003 Stock Option, Deferred Stock and Restricted Stock as of the date hereof.

Warrants

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

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

Transactions involving warrants are summarized as follows:

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The following table summarizes the changes in warrants outstanding 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.

	Weighted Average
Number of Shares	Price Per Share

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	(post-split)	(post-split)
	-----	-----
Outstanding at January 1, 2003	26,938	\$0.84
Granted	805,572	0.89
Exercised	--	--
Canceled or expired	--	--
Outstanding at December 31, 2003	832,510	0.89
Granted	16,833,699	0.47
Exercised	--	--
Canceled or expired	--	--
Outstanding at December 31, 2004	17,666,210	\$0.49

A description of our warrant arrangements and issuances is included in our financial statements for the year ended December 31, 2004 under "Note H - Stock Options and Warrants." These financial statements were included in our annual report on Form 10-KSB for the year ended December 31, 2004, as originally filed on April 19, 2005.

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

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

### 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 Chief Research Scientist and Director, Mark Witten. IR BioSciences Holdings, Inc. holds less than 1% ownership in the company. For the three month period ended June 30, 2005, we incurred expenses totaling approximately \$23,558 on a Singapore-based consultant. For the period of inception (October 30, 2002) to September 30, 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

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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; (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

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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 (Viprovox), 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; (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.

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At December 31, 2004, InOne no longer employs or has any business relationship with the spouse of Mr. Wilhelm.

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

### RELATED PARTY LOANS

In October 2003, we were loaned \$30,000 by Gerald Witten, the father of one of our founders. Pursuant to the terms of this transaction, we provided this lender with a warrant to purchase 15,000 shares of our common stock at a price of \$2.00 per share. The original duration of the loan was 180 days and was extended to one year. The interest rate was 8% per annum. This loan was repaid in October 2004.

In October 2003, we were loaned \$40,000 by Foresight Capital Corporation, a company controlled by Michael Wilhelm, our President and CEO. Pursuant to the terms of this transaction, we provided this lender with a warrant to purchase 20,000 shares of our common stock at a price of \$2.00 per share. The loan was payable upon funding of \$150,000 in debt or equity and bore interest at 8% per annum. This loan was repaid in October 2004.

In December 2003, we were loaned \$20,000 by Carol Kraft, the mother-in-law of Michael Wilhelm, our President and CEO. Pursuant to the terms of this transaction, we provided this lender with a warrant to purchase 10,000 shares of our common stock at a price of \$2.00 per share. The original duration of the loan was 180 days and was extended to one year. The interest rate was 8% per annum. This loan was repaid in October 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 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.

### 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.

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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.

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

### 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

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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 October 2003, we were loaned \$30,000 by Gerald Witten, the father of one of our founders. Pursuant to the terms of this transaction, we provided this lender with a warrant to purchase 15,000 shares of our common stock at a price of \$2.00 per share. The original duration of the loan was 180 days and was extended to one year. The interest rate was 8% per annum. This loan was repaid in October 2004.

In October 2003, we were loaned \$40,000 by Foresight Capital Corporation, a company controlled by Michael Wilhelm, our President and CEO. Pursuant to the terms of this transaction, we provided this lender with a warrant to purchase 20,000 shares of our common stock at a price of \$2.00 per share. The loan was payable upon funding of \$150,000 in debt or equity and bore interest at 8% per annum. This loan was repaid in October 2004.

In December 2003, we were loaned \$20,000 by Carol Kraft, the mother-in-law of Michael Wilhelm, our President and CEO. Pursuant to the terms of this transaction, we provided this lender with a warrant to purchase 10,000 shares of our common stock at a price of \$2.00 per share. The original duration of the loan was 180 days and was extended to one year. The interest rate was 8% per annum. This loan was repaid in October 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 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.

### STRATUM CONSULTING GROUP, LLC

On April 1, 2004, we entered into a consulting agreement with Stratum Consulting Group, LLC. ("Stratum," "The Stratum Agreement") a company controlled by Steven J. Scronic, our former Secretary. The Stratum Agreement has a term of twelve months, and calls for Stratum to provide us with financial consulting services, including but not limited to working directly with senior management regarding the business and business development, attendance at meetings, preparation of internal financial models and business plans and various

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presentations in return for the following: 200,000 shares (post-split) of our common stock upon execution of the agreement, and the number of shares of our common stock equal to \$2,500 per month for the term of the agreement. The Stratum Agreement also calls for a cash fee of an additional \$2,500 per month. There is nothing outstanding under the Stratum Agreement.

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### PRINCIPAL AND SELLING STOCKHOLDERS

This prospectus relates to the resale from time to time of up to a total of 58,194,009 shares of common stock by the selling stockholders, comprising:

- o 48,362,696 shares of our common stock that were issued to selling stockholders pursuant to transactions exempt from registration under the Securities Act of 1933; and
- o 9,831,313 shares of common stock underlying warrants that were issued to selling stockholders pursuant to transactions exempt from registration under the Securities Act of 1933.
- o The total number of shares of common stock offered for resale by the selling stockholders includes 5,534,400 shares and 2,179,200 shares of common stock issuable upon the exercise of five-year warrants with an exercise price of \$0.50 in connection with a penalty clause regarding the registration of securities sold in our Private Offering in October 2004. For each 30-day period beyond 90-days following the second closing date (October 26, 2004), we have agreed to issue to the holders of units sold in the Private Offering an additional 2% a month, or in aggregate 461,200 shares and 181,600 warrants until such a time as this Registration Statement is made effective. We have committed these shares although they remain unissued.

The following table sets forth certain information as of October 3, 2005 regarding the selling stockholders and the beneficial ownership of our common stock as to (1) each person known to us to beneficially own more than five percent of our common stock, (2) each director, (3) our executive officers, (4) all directors and executive officers as a group and (5) the shares offered by them in this prospectus. Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission, or SEC. In computing the number of shares beneficially owned by a selling stockholder and the percentage of ownership of that selling stockholder, shares of common stock underlying shares of convertible preferred stock, options or warrants held by that selling stockholder that are convertible or exercisable, as the case may be, within 60 days of October 3, 2005 are included. Those shares, however, are not deemed outstanding for the purpose of computing the percentage ownership of any other selling stockholder. Each selling stockholder's percentage of ownership in the following table is based upon 69,231,182 shares of common stock outstanding as of December 31, 2005.

Except as described below, none of the selling stockholders within the past three years has had any material relationship with us or any of our affiliates:

- o Michael Wilhelm has served as our company's Chief Executive Officer since December 2002 and on our Board of Directors since November 2002;
- o Mark Witten has served as a research scientist for our company since December 2002 and on our Board of Directors since November 2002;
- o Theodore Staahl has served on our Board of Directors since

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April 2003;

- o CDM Group, Synergos, Inc., Spelling Communications, Stratum Consulting Group, LLC, Debra Gessner, and Michael Caridi have provided services to our company within the past three years, and we agreed to issue shares of our common stock and warrants to purchase additional shares of our common stock to each of them in exchange for the settlement of outstanding indebtedness; and,
- o Steven J. Scronic, our company's former Secretary, is a control party of Stratum Consulting Group, LLC.

The term "selling stockholders" also includes any transferees, pledges, donees, or other successors in interest to the selling stockholders named in the table below. To our knowledge, subject to applicable community property laws, each person named in the table has sole voting and investment power with respect to the shares of common stock set forth opposite such person's name.

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	Number of Shares of Common stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Num of B C th
-----				
Named Executive Officers and directors:				
Michael K. Wilhelm 11007 N. Ridgeview Ct Fountain Hills, AZ 85268	8,172,814 (2)	11.4%	1,254,000 (2)	
Mark L. Witten 7032 E. Rosewood St Tucson, AZ 85710-1236	9,501,138 (3)	13.5%	1,086,000 (3)	
John N. Fermanis 11375 E. Sahuaro Dr., #2041 Scottsdale, AZ 85259	217,500 (4)	*	0	
Theodore Staahl 1329 Spanos Court Suite A-1 Modesto, CA 95356	3,489,464 (5)	5.0%	350,000 (5)	
All directors and executive officers as a group (4 persons)	21,380,916 (6)	29.5%	2,690,000 (6)	
Owners of 5% or more:				
David Harris 1501 N Campbell Ave Dept B1M Build 90 U of A				



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Tucson, AZ 85721 5,066,138 (7) 7.3% 0 (7)

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	Number of Shares of Common stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Num of B C th
-----				
Other Selling Stockholders:				
Richard Ackner 14643 Drafthorse Ln Wellington, FL 33414	148,800 (8)	*	148,800 (8)	
Wayne Adams 4845 Campo Ct Coral Gables, FL 33146	372,000 (9)	*	372,000 (9)	
Jason J. Aiello & Rachel Aiello JT WROS 714 Willowbrook Rd Staten Island, NY 10314	148,800 (10)	*	148,800 (10)	
John Alderson Hunter World Markets, Inc. 9300 Wilshire Blvd Suite 600 Beverly Hills, CA 90212	200,000 (11)	*	200,000 (11)	
Richard B. Aronson 11 Lawrence Ln Lexington, MA 02421	148,800 (8)	*	148,800 (8)	
Richard E. Beattie 101 Graystone Farm Rd White Hall, MD 21161	297,600 (12)	*	297,600 (12)	
David Benadum 13960 Fox Trail Dr. Holland, MI 49424	148,800 (8)	*	148,800 (8)	
John J. Bender 2803 S. 22nd St LaCrosse, WI 54601	148,800 (8)	*	148,800 (8)	

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	Number of Shares of Common stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Num of B C th
Lester B. Boelter 50 Shady Oak Ct Winona, MN 55987	1,116,000 (13)	1.6%	1,116,000 (13)	
Delaware Charter Guarantee Trust Co. F/B/O ML Bond Dental MP-Money Purch Keogh/FBO Betty C. Bond** P.O. Box 558 Gretna, VA 24557	148,800 (10)	*	148,800 (10)	
Delaware Charter Guarantee Trust Co. F/B/O ML Bond Dental MP-Money Purch Keogh/FBO Michael L. Bond** 601 S. Main St Gretna, VA 24557	148,800 (10)	*	148,800 (10)	
Michael L. Bond 601 S. Main St Gretna, VA 24557	297,600 (14)	*	297,600 (14)	
Roger Bouchard 32 Walnut Road Rocky Hill, CT 06067	994,625 (49)	1.4%	833,291 (49)	
Elliot Braun 3775 Park Ave Edison, NJ 08820	372,000 (15)	*	372,000 (15)	
David Briskie 15006 Beltway Dr. Addison, TX 75001	372,000 (15)	*	372,000 (15)	

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	Number of Shares of Common stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Num of B C th
Robert Burkhardt 2615 Kingston Point Fort Wayne, IN 46815	297,600 (14)	*	297,600 (14)	

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Michael Caridi 32 Cutler Road Greenwich, CT 06831	504,778 (50)	*	120,000 (50)
CDM Group Jerry Teich** 3541 East Broadway Rd Phoenix, AZ 85040	102,564 (51)	*	102,564 (51)
Edward L. Chant 226 Edward Street Suite #2 Aurora Ontario L4G 3S8 Canada	744,000 (16)	1.1%	744,000 (16)
Jerry Chitwood 3276 Lexington Rd Richmond, KY 40475	148,800 (10)	*	148,800 (10)
Salvatore Clark P.O. Box 317 Deer Park, NY 11729	272,800 (17)	*	272,800 (17)
Antonio Coladonato 2526 Harway Ave Brooklyn, NY 11214	6,200 (18)	*	6,200 (18)
Keith H. Cooper 5840 De Claire Ct Atlanta, GA 30328	297,600 (12)	*	297,600 (12)

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	Number of Shares of Common stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Num of B C th
Raymond B. Cromer 873 Westtown Rd West Chester, PA 19382	148,800 (10)	*	148,800 (10)	
William Crowell & Patricia Crowell JT WROS 9045 E. Havasupia Dr. Scottsdale, AZ 85255	148,800 (8)	*	148,800 (8)	
John Dann 895 Moraga Road, Suite 7 Lafayette, CA 94549	1,336,958 (52)	1.9%	1,183,125 (52)	1
Kris Destefano				

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2 Manchester Drive Bethpage, NY 11714	229,400 (19)	*	229,400 (19)
Sherida Downer & Paul Downer JT WROS 546 Merimont Blvd Auburn AL 36830	223,200 (20)	*	223,200 (20)
Edward Duffy 178 Hanson Ln New Rochelle, NY 10804	148,800 (10)	*	148,800 (10)
John R. Durant 1867 S. Ashe Ct Auburn, AL 36830	297,600 (12)	*	297,600 (12)
Matt Earl 5120 Aihama Dr. Woodland Hills, CA 91364	148,800 (8)	*	148,800 (8)

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	Number of Shares of Common stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Num of B C th
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Gary Ecklar 1630 N. Broadway Lexington, KY 40505	892,800 (21)	1.3%	892,800 (21)	
Robert Lee England IV 3 Montcrest Dr. Birmingham, AL 35213	148,800 (8)	*	148,800 (8)	
Roger Erickson 850 S. Boulder Hwy. 222 Henderson, NV 89015	446,400 (22)	*	446,400 (22)	
Delaware Charter Guarantee & Trust Co. F/P/O Roger Erickson** SEP IRA 850 S. Boulder Hwy. 222 Henderson, NV 89015	297,600 (12)	*	297,600 (12)	
Donn Fassero 600 Coffee Road Modesto, CA 95355	607,771 (53)	*	557,771 (53)	
Kristina Fasullo 77 Claradon Lane Staten Island, NY 10305	6,200 (18)	*	6,200 (18)	

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Alan Ferraro 7201 4th Avenue Apt. #C-14 Brooklyn, NY 11209	204,600 (23)	*	204,600 (23)
Arturo L. Filippie 1300 N. Portero Grande Dr. A Rosemead, CA 91770	148,800 (8)	*	148,800 (8)

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	Number of Shares of Common stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Num of B C th
Flagship Mortgage Co. c/o Brian Shannon** 30 East Padonia Rd Ste 207 Timonium, MD 21093	148,800 (71)	*	148,800 (71)	
William L. Fox & Lynne Fox JT WROS 450 Music Mountain Rd Falls Village, CT 06031	744,000 (16)	1.1%	744,000 (16)	
Franz Family Trust D/T/D 8/16/02 David Franz & Nicole Franz** TTEES 5553 Wellesley Dr. Calabasas, CA 91302	148,800 (8)	*	148,800 (8)	
William Christopher Frasco 532 Nugent Ave Staten Island, NY 10305	124,000 (24)	*	124,000 (24)	
Jerome French 1600 N. Foliage Dr. Wichita, KS 67206	1,653,229	2.4%	1,528,229	
Jeffrey Friedman 12074 Broadway Terrace Oakland, CA 94611	2,896,518 (55)	4.2%	2,236,468 (55)	
Janine Frisco Bernie Gallas 5200 N. Diversey Blvd. #204 Milwaukee, WI 53217	70,000 (73) 223,200 (20)	* *	70,000 (73) 223,200 (20)	

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	Number of Shares of Common stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Num of B C th
Delaware Charter GT Co. Trust Co. F/B/O Anthony Gentile** IRA 7076 Via Quito Pleasanton, CA 94566	372,000 (9)	*	372,000 (9)	
Myron Gerber 84 Gifford St. #33 New Bedford, MA 02744	297,600 (14)	*	297,600 (14)	
Debra Gessner 9331 E. Calle de Valle Scottsdale, AZ 85255	270,000 (56)	*	270,000 (56)	
William M. Goldstein 787 Trethanny Ln Wayne, PA 19087	186,000 (25)	*	186,000 (25)	
Dian Griesel 11 Stone Street, 4th Floor New York, NY 10004	300,000	*	300,000	
Gummersbach LTD Lisa Marshall 22 Victoria St Hamilton, Bermuda HMF 12	744,000 (72)	1.1%	744,000 (72)	
Steven Gurewitsch 930 5th Ave Apt. 3-G New York, NY 10021	595,200 (26)	*	595,200 (26)	

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	Number of Shares of Common stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Num of B C th
Jack Ham Revocable Living Trust Dtd 3/22/00 Jack Ham** Trustee				

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3143 Marcus Pointe Blvd Pensicola, FL 32505	297,600 (12)	*	297,600 (12)
Mark Hellner 900 West Olive Merced, CA 95348	595,200 (27)	*	595,200 (27)
Michael Hennessy 686 Bowman Rd Chamberburg, PA 17201	148,800 (8)	*	148,800 (8)
Don Jackler 246 E 51st Street, Suite 8 New York, NY 10022	792,500	1.1%	700,000
William J. Kathol 7220 S. 141st Omaha, NE 68138	744,000 (16)	1.1%	744,000 (16)
Joel Katz** c/o American Business 1205 Northern Blvd Manahasset, NY 11030	372,000 (15)	*	372,000 (15)
Robert Koch 1825 Eye St. N.W Ste 1100 Washington, DC 20006	297,600 (14)	*	297,600 (14)
Michael Kramm & Doris Kramm JT WROS 39 Rugen Dr. Harrington Pk., NJ 07640	148,800 (10)	*	148,800 (10)

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	Number of Shares of Common stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Num of B C th
----- Michael Kulick, MD Profit Shared Plan Michael Kulick, MD 450 Sutter, Suite 2620 San Francisco, CA 94118	1,122,020 (57)	1.6%	922,020 (57)	2
Indy S. Kullar 8631 Armstrong Ave Burnaby BC 999 999	223,200 (20)	*	223,200 (20)	
David Bruce Laughton 12065 Beaufait Ave				

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Northridge, CA 91326	148,800 (8)	*	148,800 (8)
Peter J. Lawrence 5 Landsdowne Crescent London W11 2NH United Kingdom	446,400 (22)	*	446,400 (22)
Myron A. Leon 2806 Saklan Indian Dr. Walnut Creek, CA 94595	148,800 (10)	*	148,800 (10)
David Lind 267 Dedham St Norfolk, MA 02056	372,000 (15)	*	372,000 (15)
Lind Family Investments LP Barry Lind**, General Partner Philip Lind**, Limited Partner 1000 West Washington St Suite #502 Chicago, IL 60607	148,800 (70)	*	148,800 (70)

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	Number of Shares of Common stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Num of B C th
Barry Lind Revocable Trust Barry Lind** Trustee U/A/D 12/19/1989 1000 West Washington St. Suite #502 Chicago, IL 60607	892,800 (21)	1.3%	892,800 (21)	
Dwight E. Long 406 Belle Glen Ln Brentwood, TN 37027	446,400 (22)	*	446,400 (22)	
Randall K. Lowry, Jr 14511 Falling Creek Dr. Houston, TX 77014	744,000 (16)	1.1%	744,000 (16)	
Steven Markowitz c/o Joseph Stevens &Co., Inc. 285 Benadict Rd Staten Island, NY 10304	744,775 (28)	1.1%	744,775 (28)	
Mike Marr 3577 Fruitville Ave Oakland, CA 94602	297,600 (14)	*	297,600 (14)	



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George F. McCabe Jr. Family Trust DTD 2/11/98 George F. McCabe** TTEE 926 Hawk Landing Frontland Park, FL 34731	372,000 (15)	*	372,000 (15)
James L. McCormack 3355 Fruitvale Rd Lincoln, CA 95648	148,800 (8)	*	148,800 (8)

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	Number of Shares of Common stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Num of B C th
John Kevin McCrary 4520 Red Fox Rd. Fort Collins, CO 80526	148,800 (8)	*	148,800 (8)	
Matthew S. Menies 52 Beach Road Massapequa, NY 11758	155,000 (29)	*	155,000 (29)	
Fabio Migliaccio 658 Henry Street Brooklyn, NY 11231	248,000 (30)	*	248,000 (30)	
Sloane M. Miles 10660 E. Mercer Dr. Scottsdale, AZ 85259	116,000	*	116,000	
E. Scott Millbury S. Shore Dr. Millbury Lane Rangely, ME 04970	148,800 (8)	*	148,800 (8)	
John Richard Miller 29 Bishop Kirk Place Oxford England UK	744,000 (16)	1.1%	744,000 (16)	
Sanford J. Miller & Babette D. Miller JT WROS 7606 Forsyth Blvd St. Louis, MO 63105	372,000 (15)	*	372,000 (15)	

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	Number of Shares of Common stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Num of B C th
Glen Miskiewicz 48 Par-La-Ville Rd. Apt. 724 Hamilton, HM11 Bermuda	744,000 (16)	1.1%	744,000 (16)	
Enrico Monaco 2230 Ocean Ave Brooklyn, NY 11229	223,200 (20)	*	223,200 (20)	
Dina Mondelli 1-74th Street Apt. #2S Brooklyn, NY 11209	6,200 (18)	*	6,200 (18)	
Steven Moore 1026 Rodeo Rd Pebble Beach, CA 93953	1,365,242 (58)	2.0%	1,215,242 (58)	
MSB Family Trust D/T/D 6/25/93 Michael Blechman** TTEE 295 Shadowood Ln Northfield, IL 60093	669,600 (31)	*	669,600 (31)	
James Mulryan & Maureen Mulryan JT WROS 9925 S. Bell Ave Chicago, IL 60643	148,800 (8)	*	148,800 (8)	
Daniel Navarro Jr. & Richard Navarro JT WROS 2036 Highway 35 N South Amboy, NJ 08879	148,800 (32)	*	148,800 (32)	

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	Number of Shares of Common stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Num of B C th
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Daniel P. Neri 308 Bordeaux Lane Cary, NC 27511	457,334 (59)	*	407,334 (59)
John G. Nesbett 11 Stone Street, 4th Floor New York, NY 10004	50,000	*	50,000
David R. Nichols & Angela S. Nichols Revocable Trust 1993 David Nichols and Angela Nichols** TTEES 2250 Applewood Ln Camarillo, CA 93012	744,000 (16)	1.1%	744,000 (16)
Allen Notowitz 2710 Victoria Mnr San Carlos, CA 94070	148,800 (8)	*	148,800 (8)
Michael O'Brien 1575 Professional Way P.O. Box 2737 Auburn, AL 36831	223,200 (20)	*	223,200 (20)
Peter Orthos 52 Stone Hill Drive S Manhasset, NY 11030	248,000 (33)	*	248,000 (33)
Alexander Orthos & Peter Orthos JT WROS 52 Stone Hill Drive S Manhasset, NY 11030	1,656,950 (34)	2.3%	1,656,950 (34)

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	Number of Shares of Common stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Num of B C th
Nelson Pan 985 Main St. Melrose, MA 02176	223,200 (20)	*	223,200 (20)	
George Paxinos 24 Vanderbilt Ave (Apt.1B) Manhasset, NY 11030	105,400 (35)	*	105,400 (35)	
Robert Petrozzo 20 Woods Lane East Hampton, NY 11937	421,600 (36)	*	421,600 (36)	

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Paul B. Poulsen & Kathleen J. Poulsen JT WROS 215 Alverado Ave Los Altos, CA 94022	297,600 (12)	*	297,600 (12)
Professional Traders Fund LLC Marc Swickle and Howard Berger** 1400 Old Country Road, Suite 206 Westbury, NY 11590	366,420 (60)	*	366,420 (60)
Progressive Ins. Services, Inc. Money Purchase Pension Plan Russell E. Davis** TTEE 205 E. Reynolds Rd Lexington, KY 40571	148,800 (8)	*	148,800 (8)
Palangat Radhakrishnan & Devika Radhakrishnan JT WROS 115 White Ave New Hyde PK., NY 11040	372,000 (15)	*	372,000 (15)

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	Number of Shares of Common stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Num of B C th
Prahalathan Rajasekaran** c/o Jupiter Asset Management 27 Cool Gardie Ave Chigwell Essex 1G7 5AX	446,400 (22)	*	446,400 (22)	
James Rathgeber 14 Richbourne Lane Melville, NY 11747	508,400 (37)	*	508,400 (37)	
Reichert, Wenner, Koch, &Provinzino Profit Sharing Plan F/B/O John Koch** 501 St. Germain St. Cloud, MN 56302	223,200 (20)	*	223,200 (20)	
Frank Restivo 1311 S. Hidden Valley Dr. W. Covina, CA 91791	148,800 (8)	*	148,800 (8)	
The Richardson Family Trust D/T/D 07/19/90				
Dennis L. Richardson &				

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Evette Richardson** TTEES 537 Ocampo Dr. Pacific Palisades, CA 90272	595,200 (38)	*	595,200 (38)
Delaware Charter Guaranty & Trust Co. FBO Stanley Riggins** IRA 1937 Whatley Dr. Auburn, AL 36830	148,800 (8)	*	148,800 (8)

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	Number of Shares of Common stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Num of B C th
Paul Sallwasser & Teri Sallwasser JT WROS 301 Windmill Palm Ave. Plantation, FL 33324	297,600 (14)	*	297,600 (14)	
Barry Saxe 35 McDaniel Rd Shady, NY 12409	2,348,600 (39)	3.4%	2,285,600 (39)	
Jody R. Saxe & Richard Saxe JT WROS 3 West Ledge Rd Marblehead, MA 01945	148,800 (8)	*	148,800 (8)	
SBM Certificate Company Eric Westbury 5101 River Road, Suite 101 Bethesda, MD 20816	900,000 (61)	1.3%	900,000 (61)	
Steve Scronic 7575 E. Indian Bend Rd. #2107 Scottsdale, AZ 85250	287,987 (62)	*	287,987 (62)	
Ronald S. Sheldon Self Directed Profit Sharing Plan & Trust Ronald S. Sheldon** TTEE 1488 Old Barn Lane Highland Pk., IL 60035	297,600 (12)	*	297,600 (12)	
Delaware Charter Guarantee & Trust Co. FBO Stanley Sides** IRA 631 Walker Ferry Rd Alexander City, AL 35010	297,600 (12)	*	297,600 (12)	

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	Number of Shares of Common stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Num of B C th
Lawrence M. Silver 225 West Hubbard Suite #600 Chicago, IL 60610	520,800 (40)	*	520,800 (40)	
Delaware Charter Guarantee Trust Co. F/B/O Richard S. Simms** II Keogh Plan 5951 S. Middlefield Rd Ste. 105 Littleton, CO 80123	148,800 (10)	*	148,800 (10)	
Joseph Sorbara 4 Windham Court Muttontown, NY 11545	744,775 (41)	1.1%	744,775 (41)	
Spelling Communications Daniel Spelling** 2211 Corinth Avenue, Suite 210 Los Angeles, CA 89064	300,532 (63)	*	286,164 (63)	
John Spiziri 5 Nettie Lane Lancaster, PA 17603	148,800 (8)	*	148,800 (8)	
Claire Spooner 111 Seaview Ct Neptune, NJ 07753	148,800 (8)	*	148,800 (8)	
Charles D. Stadterman 5620 Elgin St Pittsburgh, PA 15206	223,200 (20)	*	223,200 (20)	

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	Number of Shares of Common stock Beneficially	Percentage of Shares of Common Stock Beneficially Owned Prior	Number of Shares of Common Stock	Num of B

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	Owned Prior to Offering	to the Offering	Registered for Sale Hereby	C th
Henry Steinberg 934 Southern Drive Franklin Sq., NY 11010	148,800 (8)	*	148,800 (8)	
Warren Stout 800 E. Colorado Blvd., Suite 450 Pasadena, CA 91101	1,267,838 (65) ( )	1.8%	1,117,838 (65)	
Stratum Consulting Group, LLC Steve Scronic** 11442 E. Aster Drive Scottsdale, AZ 85259	268,800 (66)	*	268,800 (66)	
Daniel C. Strum 95 Upper Hampden Rd Monson, MA 01057	297,600 (12)	*	297,600 (12)	
Frank Sylva 450 Sylva Lane Lakeport, CA 95453	148,800 (42)	*	148,800 (42)	
Synergos, Inc. Jaye Thompson and J.T. Thompson** 2202 Timberloch Place, Suite 230 The Woodlands, TX 77380	839,091 (67)	1.2%	839,091 (67)	
Edward Taylor 6415 Boulevard East West New York, NJ 07093	58,125 (43)	*	58,125 (43)	
Andrea Todaro 55 92nd Street Apt. #2F Brooklyn, NY 11209	24,800 (44)	*	24,800 (44)	

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	Number of Shares of Common stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Num of B C th
Drew Tranchina 178-15 69th Ave. Fresh Meadows, NY 11365	68,200 (45)	*	68,200 (45)	
William S. Tyrrell 2711 Edgehill Ave Bronx, NY 10463	892,800 (21)	1.2%	892,800 (21)	

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Value Management Research AG Attn: Kevin Devine, CEO Campus Kronberg 7 D-61476 Kronberg im Taunus Germany	232,153 (68)	*	232,153 (68)
Michael Van Petten 100 N Tampa Street Suite 2200 Tampa, FL 33602	148,800 (8)	*	148,800 (8)
Louis John Ventre 1339 85th Street Brooklyn, NY 11228	124,000 (24)	*	124,000 (24)
Stephen Walker 5829 Niwot Road Longmont, CO 80503	41,162 (69)	*	39,912 (69)
John Wechsler 159 Bedford Rd Greenwich, CT 06831	186,000 (46)	*	186,000 (46)

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	Number of Shares of Common stock Beneficially Owned Prior to Offering	Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering	Number of Shares of Common Stock Registered for Sale Hereby	Num of B C th
Westrock Advisors Ed Taylor** 230 Park Ave. Suite #934 New York, NY 10169	19,375 (47)	*	19,375 (47)	
Peter T. White 122 Wilsondale St Westwood, MA 02090	372,000 (15)	*	372,000 (15)	
Robert Wilner 787 King St Rye Brook, NY 10573	595,200 (27)	*	595,200 (27)	
Olen C. Wilson 2404 Teckla Blvd Amarillo, TX 79106	223,200 (20)	*	223,200 (20)	
Tad Wilson 877 Maple Dr. Spencer, IN 47460	148,800 (8)	*	148,800 (8)	



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Jonathan H. Witherspoon 730 Yorkshire Road Winston Salem, NC 27106	148,800 (8)	*	148,800 (8)
Jeffrey Blake Woolf 80 Park Ave Apt. #7F New York, NY 10016	99,200 (48)	*	99,200 (48)
Alan J. Young 1750 Braeside Avenue Northbrook, IL 60062	520,800 (40)	*	520,800 (40)

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\* Less than 1 percent.

\*\* Beneficial owner(s) based information provided to us by the selling stockholder.

1 Represents the amount of shares that will be held by the selling stockholders after completion of this offering based on the assumption that all shares registered for sale hereby will be sold. However, the selling stockholders may offer all, some or none of the shares pursuant to this prospectus, and to our knowledge there are currently no agreements, arrangements or understanding with respect to the sale of any of the shares that may be held by the selling stockholders after completion of this offering.

2 Includes 1,788,718 shares underlying warrants that are currently exercisable at prices ranging from \$0.05 to \$2.00, 4,106,138 of which represent warrants, exercisable at \$0.05, to purchase shares held by David T. Harris. Includes 283,333 stock purchase options at with strike prices ranging from \$0.30 to \$0.40. Also includes 20,000 shares held by Michael K Wilhelm that underlie currently exercisable warrants held by one individual.

3 Includes 712,000 shares underlying warrants that are currently exercisable at prices ranging from \$0.125 to \$0.50. Includes 163,000 shares held by Mark L. Witten that underlie currently exercisable warrants held by 7 individuals.

4 Includes 74,997 common shares which have been committed. These shares to be issued per Mr. Fermanis's employment agreement. Includes 17,500 shares underlying warrants that are currently exercisable at prices ranging from \$0.25 to \$0.41.

5 Includes 93,300 common shares which have been committed These shares are being issued in conjunction with the conversion of an outstanding convertible promissory note in September 2003. Includes 203,000 shares underlying warrants that are currently exercisable at prices ranging from \$0.038 to \$1.00, 17,500 of which represent warrants to purchase shares held by David T. Harris and 17,500 of which represent warrants to purchase shares held by Mark L. Witten.

6 Includes 168,297 common shares that have been committed. Includes 150,000 common stock purchase warrants issued to Michael K. Wilhelm per his

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employment agreement. Includes 6,596,218 shares underlying warrants that are currently exercisable at prices ranging from \$0.005 to \$1.00, and 4,106,138 of which are underlying warrants to purchase shares held by David T. Harris. Includes an aggregate of 386,000 shares held by Michael, K. Wilhelm, Mark L. Witten and David T. Harris that underlie currently exercisable warrants held by 9 individuals.

- 7 Includes 4,066,138 shares held by David T. Harris that underlie currently exercisable warrants held by Foresight Capital Corporation, a company owned by Michael K. Wilhelm, and an additional 203,000 shares held by Mr. Harris that underlie currently exercisable warrants held by 8 individuals.
- 8 Includes 19,200 common shares and 9,600 common stock purchase warrants that are currently exercisable at a price of \$0.50 that have been committed due to penalty registration clause.
- 9 Includes 100,000 shares underlying warrants that are currently exercisable at \$0.50. Includes 48,000 common shares and 24,000 common stock purchase warrants that are currently exercisable at \$0.50 that have been committed due to penalty registration clause.
- 10 Includes 40,000 shares underlying warrants that are currently exercisable at \$0.50. Includes 19,200 common shares and 9,600 common stock purchase

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warrants that are currently exercisable at \$0.50 that have been committed due to penalty registration clause.

- 11 Includes 200,000 shares underlying warrants that are currently exercisable at a price of \$0.125 per share.
- 12 Includes 38,400 common shares and 19,200 common stock purchase warrants that are currently exercisable at a price of \$0.50 that have been committed due to penalty registration clause.
- 13 Includes 144,000 common shares and 72,000 common stock purchase warrants that are currently exercisable at a price of \$0.50 that have been committed due to penalty registration clause.
- 14 Includes 80,000 shares underlying warrants that are currently exercisable at \$0.50. Includes 38,400 common shares and 19,200 common stock purchase warrants that are currently exercisable at \$0.50 that have been committed due to penalty registration clause.
- 15 Includes 48,000 common shares and 24,000 common stock purchase warrants that are currently exercisable at a price of \$0.50 that have been committed due to penalty registration clause.
- 16 Includes 96,000 common shares and 48,000 common stock purchase warrants that are currently exercisable at a price of \$0.50 that have been committed due to penalty registration clause.
- 17 Includes 52,800 common shares that have been committed due to penalty registration clause.
- 18 Includes 1,200 common shares that have been committed due to penalty registration clause.
- 19 Includes 44,400 common shares that have been committed due to penalty

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registration clause.

20 Includes 28,800 common shares and 14,400 common stock purchase warrants that are currently exercisable at a price of \$0.50 that have been committed due to penalty registration clause.

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21 Includes 240,000 shares underlying warrants that are currently exercisable at \$0.50. Includes 115,200 common shares and 57,600 common stock purchase warrants that are currently exercisable at \$0.50 that have been committed due to penalty registration clause.

22 Includes 57,600 common shares and 28,800 common stock purchase warrants that are currently exercisable at a price of \$0.50 that have been committed due to penalty registration clause.

23 Includes 39,600 common shares that have been committed due to penalty registration clause.

24 Includes 24,000 common shares that have been committed due to penalty registration clause.

25 Includes 24,000 common shares and 12,000 common stock purchase warrants that are currently exercisable at a price of \$0.50 that have been committed due to penalty registration clause.

26 Includes 65,000 shares underlying warrants that are currently exercisable at \$0.50. Includes 76,800 common shares and 38,400 common stock purchase warrants that are currently exercisable at \$0.50 that have been committed due to penalty registration clause.

27 Includes 76,800 common shares and 38,400 common stock purchase warrants that are currently exercisable at a price of \$0.50 that have been committed due to penalty registration clause.

28 Includes 144,150 common shares that have been committed due to penalty registration clause.

29 Includes 30,000 common shares that have been committed due to penalty registration clause.

30 Includes 48,000 common shares that have been committed due to penalty registration clause.

31 Includes 180,000 shares underlying warrants that are currently exercisable at \$0.50. Includes 86,400 common shares and 43,200 common stock purchase warrants that are currently exercisable at \$0.50 that have been committed due to penalty registration clause.

32 Includes 20,000 shares underlying warrants that are currently exercisable at \$0.50. Includes 19,200 common shares and 9,600 common stock purchase warrants that are currently exercisable at \$0.50 that have been committed due to penalty registration clause.

33 Includes 48,000 common shares that have been committed due to penalty registration clause.

34 Includes 320,700 common shares that have been committed due to penalty registration clause.

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- 35 Includes 20,400 common shares that have been committed due to penalty registration clause.
- 36 Includes 81,600 common shares that have been committed due to penalty registration clause.
- 37 Includes 98,400 common shares that have been committed due to penalty registration clause.
- 38 Includes 160,000 shares underlying warrants that are currently exercisable at \$0.50. Includes 76,800 common shares and 38,400 common stock purchase warrants that are currently exercisable at \$0.50 that have been committed due to penalty registration clause.

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- 39 Includes 230,400 common shares and 115,200 common stock purchase warrants that are currently exercisable at a price of \$0.50 that have been committed due to penalty registration clause.
- 40 Includes 140,000 shares underlying warrants that are currently exercisable at \$0.50. Includes 67,200 common shares and 33,600 common stock purchase warrants that are currently exercisable at \$0.50 that have been committed due to penalty registration clause.
- 41 Includes 144,150 common shares that have been committed due to penalty registration clause.
- 42 Includes 20,000 shares underlying warrants that are currently exercisable at \$0.50. Includes 19,200 common shares and 9,600 common stock purchase warrants that are currently exercisable at \$0.50 that have been committed due to penalty registration clause.
- 43 Includes 11,250 common shares that have been committed due to penalty registration clause.
- 44 Includes 4,800 common shares that have been committed due to penalty registration clause.
- 45 Includes 13,200 common shares that have been committed due to penalty registration clause.
- 46 Includes 50,000 shares underlying warrants that are currently exercisable at \$0.50. Includes 24,000 common shares and 12,000 common stock purchase warrants that are currently exercisable at \$0.50 that have been committed due to penalty registration clause.
- 47 Includes 3,750 common shares that have been committed due to penalty registration clause. Dan Hunter is the Chief Operating Officer and control person of Westrock Advisors.
- 48 Includes 19,200 common shares that have been committed due to penalty registration clause.
- 49 Includes 367,264 shares underlying warrants that are currently exercisable at prices ranging from \$0.038 to \$1.00, 8,000 of which represent warrants to purchase shares held by Mark L. Witten and 8,000 of which represent warrants to purchase shares held by David T. Harris.

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- 50 Includes 424,778 shares underlying warrants that are currently exercisable at prices ranging from \$0.125 to \$0.50.
- 51 Includes 34,188 shares underlying warrants that are currently exercisable at \$0.50. Excludes 7,500 shares underlying warrants that are currently exercisable held by the owner of CDM Group. Jerry Teich is the control person of CDM Group.
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- 52 Includes 488,208 shares underlying warrants that are currently exercisable at prices ranging from \$0.25 to \$0.50.
- 53 Includes 235,924 shares underlying warrants that are currently exercisable at prices ranging from \$0.038 to \$1.00.
- 54 Includes 634,410 shares underlying warrants that are currently exercisable at prices ranging from \$0.038 to \$1.00.
- 55 Includes 40,000 shares that have been committed pending issuance. Includes 1,040,540 shares underlying warrants that are currently exercisable at prices ranging from \$0.09 to \$2.00, 62,500 of which represent warrants to purchase shares held by Mark L. Witten and 62,500 of which represent warrants to purchase shares held by David T. Harris.
- 56 Includes 90,000 shares underlying warrants that are currently exercisable at a price of \$0.50 per share.
- 57 Includes 507,340 shares underlying warrants that are currently exercisable at prices ranging from \$0.038 to \$1.00.
- 58 Includes 480,081 shares underlying warrants that are currently exercisable at prices ranging from \$0.50 to \$1.00, 37,500 of which represent warrants to purchase shares held by Mark L. Witten and 37,500 of which represent warrants to purchase shares held by David T. Harris.
- 59 Includes 50,000 shares underlying warrants that are currently exercisable, 25,000 at a price of \$1.00, 12,500 of which represent warrants to purchase shares held by Mark L. Witten and 12,500 of which represent warrants to purchase shares held by David T. Harris.
- 60 Mark Swickle and Howard Berger are the control persons of Professional Traders Fund LLC.
- 61 Eric Westbury is the control person of SBM Certificate Company.
- 62 Includes 14,464 common shares which have been committed. Includes 26,939 shares underlying warrants that are currently exercisable at \$0.278 per share. Steven J. Scronic is the control person of Stratum Consulting Group, LLC.
- 63 Includes 95,388 shares underlying warrants that are currently exercisable at a price of \$0.50. Excludes 40,000 shares and 20,000 shares underlying warrants that are currently exercisable held by the owner of Spelling Communications. Daniel Spelling is the control person of Spelling Communications.
- 64 Not used.
- 65 Includes 522,613 shares underlying warrants that are currently exercisable

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at prices ranging from \$0.038 to \$1.00.

- 66 Includes 89,600 shares underlying warrants that are currently exercisable at a price of \$0.50. Excludes 261,048 shares and 26,939 shares underlying warrants that are currently exercisable held by the owner of Stratum Consulting Group, LLC. Steven J. Scronic is the control person of Stratum Consulting Group, LLC.
- 67 Includes 279,697 shares underlying warrants that are currently exercisable at a price of \$0.50. Excludes 20,000 shares underlying warrants that are currently exercisable held by the shareholders of Synergos, Inc, Jaye Thompson and J.T. Thompson. Jaye Thompson is the control person of Synergos, Inc.
- 68 Kevin Devine is the control person of Value Management Research AG.
- 69 Includes 14,554 shares underlying warrants that are currently exercisable

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at prices ranging from \$0.35 to \$0.50.

- 70 Includes 40,000 shares underlying warrants that are currently exercisable at \$0.50. Includes 19,200 common shares and 9,600 common stock purchase warrants that are currently exercisable at \$0.50 that have been committed due to penalty registration clause. Barry Lind is the General Partner and control person of Lind Family Investments LP.
- 71 Includes 40,000 shares underlying warrants that are currently exercisable at \$0.50. Includes 19,200 common shares and 9,600 common stock purchase warrants that are currently exercisable at \$0.50 that have been committed due to penalty registration clause. Brian Shannon is the control person of Flagship Mortgage Co..
- 72 Includes 96,000 common shares and 48,000 common stock purchase warrants that are currently exercisable at a price of \$0.50 that have been committed due to penalty registration clause. Lisa Marshall is the President and control person of Gummersback LTD.
- 73 Includes 70,000 shares underlying warrants that are currently exercisable at a price of \$0.30.

We will not receive any of the proceeds from the sale of the shares by the selling stockholders. We have agreed to bear expenses incurred by the selling stockholders, up to a maximum limit of \$15,000, that relate to the registration of the shares being offered and sold by the selling stockholders, including the Securities and Exchange Commission registration fee and legal, accounting, printing and other expenses of this offering.

### DESCRIPTION OF CAPITAL STOCK

We are authorized to issue 100,000,000 shares of common stock, \$0.001 par value per share, and 10,000,000 shares of preferred stock, \$0.001 par value per share. The following description of our capital stock does not purport to be complete and is governed by and qualified by our certificate of incorporation and bylaws, which are included as exhibits to the registration statement of which this prospectus forms a part, and by the provisions of applicable Delaware law.

### COMMON STOCK

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As of December 31, 2005, we had 69,231,182 shares of common stock outstanding, which were held of record and beneficially by approximately 520 stockholders. We also have committed to the issuance of 455,441 common shares. Additionally, in regard to the penalty for delayed registration, pursuant to the terms of our October 2004 Private Placement, we have committed to the issuance of 5,534,400 common shares. As of December 31, 2005, there were 13,854,669 shares of common stock underlying outstanding warrants. Options to purchase 63,212 shares of common stock had been granted or were outstanding outside our 2003 Stock Option, Deferred Stock and Restricted Stock Plan and 253,030 options had been granted or were outstanding under our 2003 Stock Option, Deferred Stock and Restricted Stock Plan; 174,784 shares remain available for issuance under this plan.

The holders of our common stock are entitled to one (1) vote per share on all matters submitted to a vote of our stockholders. In addition, such holders are entitled to receive ratably such dividends, if any, as may be declared from time to time by our Board of Directors out of funds legally available therefore. No dividends may be paid on the common stock until all accrued but unpaid dividends on the shares of our preferred stock have been paid. In the event of the dissolution, liquidation or winding up of our company, the holders of common stock are entitled to share ratably in all assets remaining after payment of all liabilities of our company and the preference amount distributable to the holders of the shares of preferred stock. The holders of common stock do not have any subscription, redemption or conversion rights, nor do they have any preemptive or other rights to acquire or subscribe for additional, unissued or treasury shares.

Pursuant to our bylaws, except for any matters which pursuant to Delaware law require a greater percentage vote for approval, the holders of a majority of the outstanding shares of common stock, if present in person or by proxy, are sufficient to constitute a quorum for the transaction of business at meetings of our stockholders. Except as to any matters which pursuant to Delaware law require a greater percentage vote for approval, the affirmative vote

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of the holders of a majority of the shares of common stock present in person or by proxy at any meeting (provided a quorum is present) is sufficient to authorize, affirm or ratify any act or action, including the election of our Board of Directors.

The holders of the common stock do not have cumulative voting rights. Accordingly, the holders of more than half of the outstanding shares of common stock can elect all of the directors to be elected in any election, if they choose to do so. In such event, the holders of the remaining shares of common stock would not be able to elect any directors. Our Board of Directors is empowered to fill any vacancies on the Board created by the resignation, death or removal of directors.

In addition to voting at duly called meetings at which a quorum is present in person or by proxy, Delaware law and our bylaws provide that stockholders may take action without the holding of a meeting by written consent or consents signed by the holders of a majority of the outstanding shares of our capital stock entitled to vote thereon. Prompt notice of the taking of any action without a meeting by less than unanimous consent of the stockholders will be given to those stockholders who do not consent in writing to the action. The purposes of this provision are to facilitate action by stockholders and to reduce the corporate expense associated with special meetings of stockholders.

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### MARKET PRICE OF OUR COMMON STOCK

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

- o Our ability to obtain additional financing and, if available, the terms and conditions of the financing;
  - o Our financial position and results of operations;
  - o Biological or medical discoveries by competitors;
  - o The results of preclinical studies and clinical trials by us, our collaborators or our competitors;
  - o Concern as to, or other evidence of, the safety or efficacy of our proposed products or our competitors' products;
  - o Announcements of technological innovations or new products by us or our competitors;
  - o U.S. and foreign governmental regulatory actions;
  - o Delays in the conduct or analysis of our preclinical or clinical studies;
  - o Unfavorable results from preclinical or clinical studies;
  - o Unfavorable developments concerning patents or other proprietary rights;
  - o Unfavorable domestic or foreign regulatory developments;
  - o Actual or anticipated changes in drug reimbursement policies;
  - o Developments with our collaborators, if any;
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- o Developments concerning patent or other proprietary rights of us or our competitors (including litigation);
  - o Status of litigation;
  - o Period-to-period fluctuations in our operating results;
  - o Changes in estimates of our company's performance by any securities analysts;
  - o New regulatory requirements and changes in the existing regulatory environment;



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- o Market conditions for life science stocks in general.
- o The issuance of new equity securities pursuant to a future offering;
- o Changes in interest rates;
- o Competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- o Variations in quarterly operating results;
- o Change in financial estimates by securities analysts; o The depth and liquidity of the market for our common stock;
- o Investor perceptions of our company and the technologies industries generally; and
- o General economic and other national conditions.

Trading in our securities could be subject to extreme price fluctuations that could adversely affect your investment. The market prices for securities of life sciences companies, particularly those that are not profitable, have been highly volatile, especially recently. Publicized events and announcements may have a significant impact on the market price of our common stock. The factors listed above may have the effect of temporarily or permanently driving down the price of our common stock. In addition, the stock market from time to time experiences extreme price and volume fluctuations which particularly affect the market prices for emerging and life sciences companies, such as ours, and which are often unrelated to the operating performance of the affected companies. For example, our stock price has ranged from \$0.09 to \$1.00 between January 1, 2004 and February 16, 2006.

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

### PREFERRED STOCK

Under our certificate of incorporation, shares of our preferred stock may, without any action by our stockholders, be issued by our Board of Directors from time to time in one or more series for such consideration and with such relative rights, privileges and preferences as the Board may determine. Accordingly, our Board of Directors has the power, without stockholder approval, to fix the dividend rate and to establish the provisions, if any, relating to voting rights, redemption rate, sinking fund, liquidation preferences and conversion rights for any series

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of preferred stock (subject to the preferences of the shares of common stock offered hereby) issued in the future, which could adversely affect the voting power or other rights of the holders of common stock.

Our Board of Directors' authority to issue preferred stock provides a convenient vehicle in connection with possible acquisitions and other corporate purposes, but could have the effect of making it more difficult for a person or group to gain control of our company. As of the date of the prospectus, there are no shares of preferred stock outstanding, and we do not have present plans to issue any shares of preferred stock or designate any series of preferred stock.

### STOCK OPTIONS

As of December 31, 2005, there were 316,242 outstanding stock options at a weighted average exercise price of \$5.31, of which 253,030 are at an average price of \$0.37 per share and were granted under our 2003 Stock Option, Deferred Stock and Restricted Stock Plan and 63,212 shares at a weighted average exercise price of \$25.00 per share that were granted outside of our 2003 Stock Option, Deferred Stock and Restricted Stock Plan. There are 174,784 shares reserved for future grant under our 2003 Stock Option, Deferred Stock and Restricted Stock Plan.

Our Board of Directors has approved the issuance of a nonstatutory option to purchase 1,896,970 shares at 110% of the fair market value per share to our Chief Executive Officer under our 2003 Stock Option, Deferred Stock and Restricted Stock Plan. Due to the fact that there are currently not enough shares available under our 2003 Stock Option, Deferred Stock and Restricted Stock Plan to grant these options to our Chief Executive Officer, we have not yet made a commitment to issue these options. We recognize that if, at such a time as the Company's 2003 Stock Plan is amended to authorize additional shares, a commitment will be made and the options granted.

### WARRANTS

As of December 31, 2005, there were outstanding warrants to purchase 13,854,669 shares of our common stock with exercise prices ranging from \$0.04 to \$2.00 per share.

### DELAWARE ANTI-TAKEOVER LAW AND CHARTER AND BYLAW PROVISIONS

We are subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, this statute prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date that the person became an interested stockholder unless, with certain exceptions, the business combination or the transaction in which the person became an interested stockholder is approved in a prescribed manner. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the stockholder.

Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns or within three years prior, did own 15% or more of the corporation's voting stock. These provisions may have the effect of delaying, deferring or preventing a change in control of us without further action by our stockholders.

Our certificate of incorporation and bylaws contain provisions that could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control of our company, including changes a stockholder might consider favorable. In particular, our

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certificate of incorporation and bylaws, as applicable, among other things, will:

- o provide our board of directors with the ability to alter our bylaws without stockholder approval;
- o provide that special meetings of stockholders can only be called by our Board of Directors or by a committee of our Board of Directors that has been duly designated by the Board and whose powers and authority included the power to call such meetings;
- o provide for an advance notice procedure with regard to the nomination of candidates for election as directors and with regard to business to be brought before a meeting of stockholders;

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- o provide that vacancies on our board of directors may be filled by a majority of directors in office, although less than a quorum; and
- o allow us to issue up to 10,000,000 shares of preferred stock with rights senior to those of the common stock and that otherwise could adversely affect the rights and powers, including voting rights, of the holders of common stock. In some circumstances, this issuance could have the effect of decreasing the market price of our common stock, as well as having the anti-takeover effects discussed above.

Such provisions may have the effect of discouraging a third-party from acquiring us, even if doing so would be beneficial to our stockholders. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by them, and to discourage some types of transactions that may involve an actual or threatened change in control of our company. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage some tactics that may be used in proxy fights. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company outweigh the disadvantages of discouraging such proposals because, among other things, negotiation of such proposals could result in an improvement of their terms. However, these provisions could have the effect of discouraging others from making tender offers for our shares that could result from actual or rumored takeover attempts. These provisions also may have the effect of preventing changes in our management.

### BROKER-DEALER REQUIREMENTS FOR "PENNY STOCK" TRANSACTIONS

Our common stock is considered to be a "penny stock" since it meets one or more of the definitions in Rules 15g-2 through 15g-6 promulgated under Section 15(g) of the Securities Exchange Act of 1934, as amended. Section 15(g) of the Securities Exchange Act of 1934, as amended, and Rule 15g-2 promulgated thereunder by the SEC require broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document before effecting any transaction in a penny stock for the investor's account. Compliance with this and other requirements may make it more difficult for holders of our common stock to resell their shares to third parties or to otherwise dispose of them in the market or otherwise.

### TRANSFER AGENT AND REGISTRAR

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The transfer agent for our common stock is Stalt, Inc., located at 671 Oak Grove Avenue, Suite C, Menlo Park, California 94025.

### SHARES ELIGIBLE FOR FUTURE SALE

As of December 31, 2005, we had outstanding 69,231,182 shares of common stock.

#### RULE 144

Of our outstanding shares, 5,989,664 shares of common stock are immediately eligible for sale in the public market without restriction or further registration under the Securities Act. All other outstanding shares of our common stock are "restricted securities" as such term is defined under Rule 144, in that such shares were issued in private transactions not involving a public offering and may not be sold in the absence of registration other than in accordance with Rules 144 or another exemption from registration under the Securities Act.. If shares are purchased by our "affiliates" as that term is defined in Rule 144 under the Securities Act of 1933, their sales of shares would be governed by the limitations and restrictions that are described below.

In general, under Rule 144 as currently in effect, a person (or persons whose shares are aggregated) who has beneficially owned shares of our common stock for at least one year, including any person who may be deemed to be an "affiliate" (as the term "affiliate" is defined under the Securities Act of 1933), would be entitled to sell, within any three-month period, a number of shares that does not exceed the greater of 1% of the number of shares of common stock then outstanding, which as of February 16, 2006 would equal approximately 692,311 shares.

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Sales under Rule 144 are also governed by other requirements regarding the manner of sale, notice filing and the availability of current public information about us. Under Rule 144, however, a person who is not, and for the three months prior to the sale of such shares has not been, an affiliate of the issuer is free to sell shares that are "restricted securities" which have been held for at least two years without regard to the limitations contained in Rule 144. The selling stockholders will not be governed by the foregoing restrictions when selling their shares pursuant to this prospectus.

#### RULE 144(K)

Under Rule 144(k), a person who is not deemed to have been one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned the shares proposed to be sold for at least two years, including the holding period of any prior owner other than an affiliate, is entitled to sell such shares without complying with the manner of sale, notice filing, volume limitation or notice provisions of Rule 144.

#### SEC POSITION ON RULE 144 SALES

In November 2000, we changed our name to GPN Network, Inc. In July 2001, we discontinued the operations of GPN Network, Inc. in their entirety and began looking for appropriate merger partners. Our objective became the acquisition of an operating company with the potential for growth in exchange for our securities. In July 2003, we effected a reverse merger with ImmuneRegen BioSciences, Inc. and adopted our current business model.

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Prior to the merger with ImmuneRegen Biosciences, Inc., we were a blank check company and did not have any operations or receive any revenues since inception. A "blank check" company is a development stage company that has no specific business plan or purpose or has indicated its business plan is to engage in a merger or acquisition with an unidentified company or companies, or other entity or person.

The Securities and Exchange Commission has taken the position that promoters or affiliates of a blank check company and their transferees, both before and after a business combination, would act as an "underwriter" under the Securities Act when reselling the securities of a blank check company because their resale transactions would appear to be designed to distribute or redistribute securities to the public without compliance with the registration requirement of the Securities Act. Accordingly, the Securities and Exchange Commission believes that those securities can be resold only through a registered offering and that Rule 144 would not be available for those resale transactions despite technical compliance with the requirements of Rule 144. As of October 3, 2005, 366,420 shares of our outstanding 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 or affiliates (or their transferees) of our prior company, GPN Networks, Inc.. These shares are being registered hereby.

Additionally, stockholders who obtained securities directly from a blank check issuer and through promoters and affiliates, cannot use Rule 144 to resell their securities, since their resale transactions would appear to be designed to distribute or redistribute securities to the public without compliance with the registration requirement of the Securities Act. As a result, this policy applies to stockholders of ImmuneRegen Biosciences, Inc., prior to the merger with our company.

### PLAN OF DISTRIBUTION

The selling stockholders, and any of their pledgees, assignees and successors-in-interest, may, from time to time, sell any or all of their shares of our common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

- o ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
  - o block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
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- o purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
  - o an exchange distribution in accordance with the rules of the applicable exchange;
  - o privately negotiated transactions;
  - o settlement of short sales entered into after the date of this prospectus;

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- o broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- o a combination of any such methods of sale; or
- o through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise.

The selling stockholders may also sell shares under Rule 144 under the Securities Act of 1933, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. Each selling stockholder does not expect these commissions and discounts relating to its sales of shares to exceed what is customary in the types of transactions involved.

In connection with the sale of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may, after the date of this prospectus, also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholders has informed us that it does not have any agreement or understanding, directly or indirectly, with any person to distribute our common stock.

The shares of common stock underlying the warrants issued to those selling stockholders who, as indicated in the Selling Stockholder table above, received such warrants as part of compensation pursuant to a placement agency agreement between us and Joseph Stevens & Co. are restricted in accordance with Rule 2710(g)(I) of the NASD Conduct Rules. Accordingly, those selling stockholders shall not directly or indirectly, offer, sell, agree to offer or sell, transfer, assign, pledge, hypothecate or subject to hedging, short sale, derivative, put or call transaction such shares for a period of 180 days after the date this registration statement is declared effective by the SEC

We are required to pay certain fees and expenses incurred by us incident to the registration of the shares. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Because selling stockholders may be deemed to be "underwriters" within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act. In addition, any securities covered

by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. Each selling stockholder has advised us that they have not entered into any agreements, understandings or arrangements with any underwriter or broker-dealer regarding the sale of the resale shares. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the selling stockholders.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the shares may be resold by the selling stockholders without registration and without regard to any volume limitations by reason of Rule 144(k) under the Securities Act or any other rule of similar effect or (ii) all of the shares have been sold pursuant to the prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Securities Exchange Act of 1934, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to our common stock for a period of two business days prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of our common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale.

#### DISCLOSURE OF COMMISSION POSITION OF INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Under Section 145 of the General Corporation Law of the State of Delaware, we can indemnify our directors and officers against liabilities they may incur in such capacities, including liabilities under the Securities Act of 1933, as amended (the "Securities Act"). Our certificate of incorporation provides that, pursuant to Delaware law, our directors shall not be liable for monetary damages for breach of the directors' fiduciary duty of care to us and our stockholders. This provision in the certificate of incorporation does not eliminate the duty of care, and in appropriate circumstances equitable remedies such as injunctive or other forms of nonmonetary relief will remain available under Delaware law. In addition, each director will continue to be subject to liability for breach of the director's duty of loyalty to us or our stockholders, for acts or omissions not in good faith or involving intentional misconduct or knowing violations of the law, for actions leading to improper personal benefit to the director, and for payment of dividends or approval of stock repurchases or redemptions that are unlawful under Delaware law. The provision also does not affect a director's responsibilities under any other law, such as the federal securities laws or state or federal environmental laws.

Our bylaws provide for the indemnification of our directors to the fullest extent permitted by the Delaware General Corporation Law. Our bylaws further provide that our Board of Directors has sole discretion to indemnify our officers and other employees. We may limit the extent of such indemnification by

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individual contracts with our directors and executive officers, but have not done so. We are required to advance, prior to the final disposition of any proceeding, promptly on request, all expenses incurred by any director or executive officer in connection with that proceeding on receipt of an undertaking by or on behalf of that director or executive officer to repay those amounts if it should be determined ultimately that he or she is not entitled to be indemnified under our bylaws or otherwise. We are not, however, required to advance any expenses in connection with any proceeding if a determination is reasonably and promptly made by our Board of Directors by a majority vote of a quorum of disinterested Board members that (a) the party seeking an advance acted in bad faith or deliberately breached his or her duty to us or our stockholders and (b) as a result of such actions by the party seeking an advance, it is more likely than not that it will ultimately be determined that such party is not entitled to indemnification pursuant to the applicable sections of our bylaws.

We have been advised that in the opinion of the Securities and Exchange Commission, insofar as indemnification for liabilities arising under the Securities Act of 1933 (the "Securities Act") may be permitted to our

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directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. In the event a claim for indemnification against such liabilities (other than our payment of expenses incurred or paid by our director, officer or controlling person in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

### LEGAL MATTERS

The validity of the common stock offered by this prospectus will be passed upon for us by Kirkpatrick & Lockhart Nicholson Graham LLP, Los Angeles, California.

### EXPERTS

The financial statements appearing in this Prospectus and Registration Statement have been audited by Russell Bedford Stefanou Mirchandani LLP, independent accountants; to the extent and for the periods indicated in their report appearing elsewhere herein, and are included in reliance upon such report and upon the authority of such firms as experts in accounting and auditing.

### ADDITIONAL INFORMATION

We filed with the Securities and Exchange Commission a registration statement on Form SB-2 under the Securities Act of 1933 for the shares of common stock in this offering. This prospectus does not contain all of the information in the registration statement and the exhibits and schedule that were filed with the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and the exhibits and schedule that were filed with the registration statement. Statements contained in this prospectus about the contents of any contract or any other document that



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is filed as an exhibit to the registration statement are not necessarily complete, and we refer you to the full text of the contract or other document filed as an exhibit to the registration statement. A copy of the registration statement and the exhibits and schedules that were filed with the registration statement may be inspected without charge at the Public Reference Room maintained by the Securities and Exchange Commission at 100 F Street, N.E., Washington, D.C. 20549, and copies of all or any part of the registration statement may be obtained from the Securities and Exchange Commission upon payment of the prescribed fee. Information regarding the operation of the Public Reference Room may be obtained by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Securities and Exchange Commission maintains a web site that contains reports, proxy and information statements, and other information regarding registrants that file electronically with the SEC. The address of the site is [www.sec.gov](http://www.sec.gov).

We are subject to the information and periodic reporting requirements of the Securities Exchange Act of 1934, and in accordance with the Securities Exchange Act of 1934, we file annual, quarterly and special reports, and other information with the Securities and Exchange Commission. These periodic reports and other information are available for inspection and copying at the regional offices, public reference facilities and website of the Securities and Exchange Commission referred to above.

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

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

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of IR Biosciences Holdings, Inc., a development stage company, as of December 31, 2004, and the results of its operations and its cash flows for the years ended December 31, 2004 and 2003 and for the period October 30, 2002 (date of inception) through December 31, 2004, in conformity with accounting principles generally accepted in the United States of America.

/s/ RUSSELL BEDFORD STEFANOU MIRCHANDANI LLP

-----  
Russell Bedford Stefanou Mirchandani LLP

New York, New York  
March 4, 2005

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

	December 31, 2004
	-----
Assets	
Current assets	
Cash and cash equivalents	\$ 970,114
Prepaid services and other current assets	6,713
	-----
Total current assets	976,827
Licensed proprietary rights, net	7,320
Furniture and equipment, net	6,500
	-----
Total assets	\$ 990,647
	=====
Liabilities and Stockholders' Equity	
Current liabilities	
Current portion of notes payable, net of discount	75,993
Accounts payable and accrued liabilities	307,301
	-----
Total current liabilities	383,294
Commitments and Contingencies	
Stockholders' Equity	
Preferred stock, 0.001 par value:	
10,000,000 shares authorized, no shares issued and outstanding	0
Common stock, \$0.001 par value; 100,000,000 shares authorized;	
62,423,388 shares issued and outstanding at December 31, 2004	62,423
Additional paid-in capital	7,922,943
Deferred compensation	(169,986)
Deficit accumulated during the Development Stage	(7,208,027)
Total stockholder's equity	607,353
	-----
Total liabilities and stockholders' equity	\$ 990,647
	=====

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

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

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

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

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

	Common Stock		Additional	Deferr
	-----	-----	Paid-In	Compensa
	Shares	Amount	Capital	-----
	-----	-----	-----	-----
Balance at October 30, 2002 (date of inception)	--	\$	--	\$
	-----	-----	-----	-----

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Shares of common stock issued at \$0.0006 per share to founders for license of proprietary right in December 2002	16,612,276	16,612	(7,362)	
Shares of common stock issued at \$0.0006 per share to founders for services rendered in December 2002	1,405,310	1,405	(623)	
Shares of common stock issued at \$0.1671 per share to consultants for services rendered in December 2002	53,878	54	8,946	(9
Sale of common stock for cash at \$0.1671 per share in December 2002	185,578	186	30,815	
Net loss for the period from inception (October 30, 2002) to December 31, 2002	--	--	--	
Balance at December 31, 2002 (reflective of stock splits)	18,257,042	18,257	31,776	(9
Shares granted to consultants at \$0.1392 per share for services rendered in January 2003	98,776	99	13,651	
Sale of shares of common stock for cash at \$0.1517 per share in January 2003	329,552	330	49,670	
Shares granted to consultants at \$0.1392 per share for services rendered in March 2003	154,450	154	21,346	
Conversion of notes payable to common stock at \$0.1392 per share in April 2003	1,436,736	1,437	198,563	
Shares granted to consultants at \$0.1413 per share for services rendered in April 2003	14,368	14	2,016	
Sale of shares of common stock for cash at \$0.2784 per share in May 2003	17,960	18	4,982	
Sales of shares of common stock for cash at \$0.2784 per share in June 2003	35,918	36	9,964	
Conversion of notes payable to common stock at \$0.1392 per share in June 2003	718,368	718	99,282	
Beneficial conversion feature associated with notes issued in June 2003	--	--	60,560	
Amortization of deferred compensation	--	--	--	9
Costs of GPN Merger in July 2003	2,368,130	2,368	(123,168)	
Value of warrants issued with extended notes payable in October 2003	--	--	189,937	
Value of Company warrants issued in conjunction with fourth quarter notes payable issued October through December 2003	--	--	207,457	
Value of warrants contributed by founders in conjunction with fourth quarter notes				

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payable issued October through December 2003	--	--	183,543	
Value of warrants issued for services in October through December 2003	--	--	85,861	
Net loss for the twelve month period ended December 31, 2003	--	--	--	
Balance at December 31, 2003	23,431,300	23,431	1,035,441	
Shares granted at \$1.00 per share pursuant to the Senior Note Agreement in January 2004	600,000	600	599,400	(600)
Shares issued at \$1.00 per share to a consultant for services rendered in January 2004	800,000	800	799,200	(800)
Shares issued to a consultant at \$0.62 per share for services rendered in February 2004	40,000	40	24,760	(24)
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	
Shares issued to consultants at \$0.32 per share for services rendered in March 2004	91,600	92	29,220	
Shares to be issued to consultant at \$0.41 per share in April 2004 for services to be rendered through March 2005	--	--	--	(82)
Shares granted pursuant to the New Senior Note Agreement in April 2004	600,000	600	149,400	(150)
Shares issued to officer at \$0.32 per share for services rendered in April 2004	200,000	200	63,800	
Conversion of note payable to common stock at \$0.10 per share in May 2004	350,000	350	34,650	

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

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

	Common Stock		Additional Paid-In Capital	Deferr Compensa
	Shares	Amount		
Beneficial Conversion Feature associated with note payable in May 2004	--	--	35,000	
Issuance of warrants to officers and founder for services rendered in May 2004	--	--	269,208	
Shares to a consultant at \$0.20 per share as a due dilligence fee in May 2004	125,000	125	24,875	
Shares issued to a consultant at \$1.00 per share for services to be rendered over twelve months beginning May 2004	500,000	500	499,500	(500)
Benefial Conversion Feature associated with notes payable issued in June 2004	--	--	3,000	
Issuance of warrants to note holders in April, May, and June 2004	--	--	17,915	
Issuance of warrants to employees and consultants for services rendered in April through June 2004	--	--	8,318	
Shares issued in July to a consultant at \$0.10 for services to be rendered through July 2005	250,000	250	24,750	(25)
Shares issued to a consultant in July and September at \$0.41 per share for services to be rendered through April 2005	200,000	200	81,800	
Shares issued to a consultant in September at \$0.12 to \$0.22 for services rendered through September 2004	127,276	127	16,782	
Shares issued in July to September 2004 as interest on note payable	300,000	300	35,700	
Issuance of warrants with notes payable in July and August 2004	--	--	72,252	
Accrued deferred compensation in August 2004 to a consultant for 100,000 shares at \$0.10 per share, committed but unissued	--	--	--	(10)
Shares issued in August 2004 at \$0.14 to a consultant for services to be performed through October 2004	100,000	100	13,900	(14)
Shares issued in August 2004 at \$0.125 per				

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share for conversion of \$30,000 demand loan	240,000	240	29,760	
Shares issued in August 2004 at \$0.16 per share to a consultant for services provided	125,000	125	19,875	
Shares issued to employees at \$0.16 to \$0.25 per share	48,804	49	8,335	
Commitment to issue 100,000 shares of stock to a consultant at \$0.23 per share for services to be provided through September 2005	--	--	--	(23
Sale of stock for cash in 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	--	--	112,697	
Issuance of stock to investment bankers in October 2004 for commissions earned	4,900,000	4,900	(4,900)	
Conversion of accounts payable to stock in October at \$0.125 per share	1,257,746	1,258	107,382	
Value of warrants issued with accounts payable conversions	--	--	48,579	
Conversion of demand loan to stock in October at \$0.11 per share	93,300	93	10,170	
Forgiveness of notes payable in October 2004	--	--	36,785	
Issuance of stock to officer and director at \$0.125 per share in October for conversion of liability	1,440,000	1,440	122,493	
Value of warrants issued with officer and director conversion of liabilities	--	--	56,067	
Conversion of debt and accrued interest to common stock at \$0.075 to \$0.125 per share	6,703,151	6,703	417,514	
Value of warrants issued with conversion of debt	--	--	191,111	
Conversion of note payable in October into common stock at \$0.075 per share	67,613	68	4,932	
Issuance of warrants to note holders in October 2004	--	--	112,562	
Value of shares issued to CFO as compensation	100,000	100	34,900	
Value of warrants issued to members of advisory committees in November and December	--	--	16,348	
Beneficial conversion feature associated with notes payable	--	--	124,709	



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Shares issued in error to be cancelled	(9,002)	(9)	9	
Amortization of deferred compensation through December 31, 2004	--	--	--	2,729
Loss for the twelve months ended December 31, 2004	--	--	--	
Balance at December 31, 2004	62,423,388	62,423	7,922,943	(169)

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

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

	For the Twelve Months Ended December 31, 2004	For the Twelve Months Ended December 31, 2003	Cum from (Oct 20 Dec
Cash flows from operating activities:			
Net loss	\$ (5,305,407)	\$ (1,856,702)	\$ (7,2
ADJUSTMENTS TO RECONCILE NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:			
Non-cash compensation	3,284,577	114,641	3,4
Interest expense	83,776	68,624	1
Amortization of discount on notes payable	704,633	302,302	1,0
Depreciation and amortization	13,255	12,685	
Changes in operating assets and liabilities:			
Prepaid services and other assets	29,130	(35,842)	
Accounts payable and accrued expenses	148,854	397,402	5
NET CASH USED IN OPERATING ACTIVITIES	(1,041,182)	(996,890)	(2,0
Cash flows from investing activities:			
Acquisition of property and equipment	(4,783)	(3,304)	
NET CASH USED IN INVESTING ACTIVITIES	(4,783)	(3,304)	
Cash flows from financing activities:			
Net proceeds from notes payable	32,500	1,186,000	1,2
Principal payments on notes payable	--	(250,000)	(2
Shares of stock sold for cash	1,973,045	65,000	2,0
Officer repayment of amounts paid on behalf of officer	--	19,880	
Cash paid on behalf of officer	--	(19,880)	(
Cash paid on amount due to officer	--	(22,427)	(
NET CASH PROVIDED BY FINANCING ACTIVITIES	2,005,545	978,573	3,0

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Net increase in cash and cash equivalents	959,580	(21,621)	9
Cash and cash equivalents at beginning of period	10,534	32,155	
Cash and cash equivalents at end of period	\$ 970,114	\$ 10,534	\$ 9

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

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

Non-cash investing and financing activities:

	For the Twelve Months Ended December 31, 2004	For the Twelve Months Ended December 31, 2003	Cum from (Oct 20 Dec
Supplemental Disclosures of Cash Flow Information:			
Acquisition and Capital Restructure:			
Assets acquired	\$ -	\$ -	\$
Liabilities assumed	-	(120,799)	
Common stock retained	-	(2,369)	
Adjustment to additional paid in capital	-	123,168	
Organization costs	-	350,000	
Total consideration paid	\$ -	\$ 350,000	\$
Cash paid during the period for interest	\$ 54	\$ 41,793	\$
Cash paid during the period for taxes	\$ --	\$ --	\$
Common stock issued in exchange for proprietary rights	\$ --	\$ --	\$
Common stock issued in exchange for services	\$ 2,878,006	\$ 37,280	\$
Common stock issued in exchange for previously incurred debt and accrued interest	\$ 695,591	\$ 300,000	\$
Common stock issued in exchange as interest	\$ 36,000	\$ --	\$

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Amortization of beneficial conversion feature	\$ 162,709	\$ 60,560	\$
Stock options and warrants issued in exchange for services rendered	\$ 406,571	\$ 85,861	\$
Debt and accrued interest forgiveness from note holders	\$ 36,785	\$ --	\$
Common stock issued in satisfaction of accounts payable	\$ 157,219	\$ --	\$
Common stock issued in satisfaction of amounts due to an Officer and a Director	\$ 180,000	\$ --	\$

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

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

NOTE A - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

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

Nature of Business

IR Biosciences Holdings Inc. ("Company") formerly GPN Network, Inc. ("GPN") is currently a development stage company under the provisions of Statement of Financial Accounting Standards ("SFAS") No. 7. The Company, which was incorporated under the laws of the State of Delaware on October 30, 2002, is a biotechnology company and plans to develop and market applications utilizing modified substance P, a naturally occurring immunomodulator. From its inception through the date of these financial statements, the Company has recognized minimal revenues and has incurred significant operating expenses.

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

Acquisition and Corporate Restructure

On July 20, 2003 ImmuneRegen Biosciences Inc. ("ImmuneRegen") entered into an

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

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

Effective with the Agreement, all previously outstanding common stock, preferred stock, options and warrants owned by the Company's shareholders were exchanged for an aggregate of 21,063,170 (post-split) shares of GPN common stock. The value of the stock that was issued was the historical cost of GPN's net tangible assets, which did not differ materially from their fair value.

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

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

### Use of Estimates

-----

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

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

### NOTE A - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

#### 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 accounts for its long-lived assets under the provision of Statements of Financial Accounting Standards No. 121, "Accounting for the Impairment of

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Long-Lived Assets and for Long-Lived Assets To Be Disposed Of." The Company's long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Events relating to recoverability may include significant unfavorable changes in business conditions, recurring losses, or a forecasted inability to achieve break-even operating results over an extended period. The Company evaluates the recoverability of long-lived assets based upon forecasted undiscounted 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.

### Income Taxes

-----

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

### Net Loss Per Common Share

-----

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

### Liquidity

-----

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

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

NOTE A - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

### Research and Development

-----

The Company accounts for research and development costs in accordance with the

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

### Concentrations of Credit Risk

-----

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

### Comprehensive Income

-----

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

### Stock Based Compensation

-----

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure-an amendment of SFAS 123." This statement amends SFAS No. 123, "Accounting for Stock-Based Compensation," to provide alternative methods of transition for a voluntary charge to the fair value based method of accounting for stock-based employee compensation. In addition, this statement amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The Company has chosen to continue to account for stock-based compensation using the intrinsic value method prescribed in APB Opinion No. 25 and related interpretations. Accordingly, compensation expense for stock options is measured as the excess, if any, of the fair market value of the Company's stock at the date of the grant over the exercise

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

### NOTE A - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

#### Stock Based Compensation (continued)

-----

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

#### Segment Information

-----

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

#### Fair Value of Financial Instruments

-----

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

#### Property and Equipment

-----

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

Computer equipment	3 years
Furniture	7 years

#### Website Development Costs

-----

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

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### Advertising

-----

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

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

### NOTE A - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

#### Reclassifications

-----

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

#### New Accounting Pronouncements

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

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



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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

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NOTE A - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

New Accounting Pronouncements (continued)

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

NOTE B - PROPERTY, PLANT AND EQUIPMENT

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

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

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

### NOTE C - INTANGIBLE ASSETS

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

The Company has licensed from its founders certain proprietary rights which the Company intends to utilize in the execution of its business plan. Consideration for this license was the issuance of 16,612,276 shares (post-split) of the Company's restricted common, valued at the shares' par value of \$0.001 per share, aggregating \$ 9,250. These proprietary rights are being amortized over the term of the license agreement, or ten years.

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

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

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

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### NOTE D - ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

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

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

### NOTE E - RELATED-PARTY TRANSACTIONS

Consulting Agreements

-----

On December 16, 2002, the Company entered into consulting agreements (the "Consulting Agreements") with its two founders and chief research scientists (the "Consultants"). The Consulting Agreements were on a month-to-month basis. Under the terms of the Consulting Agreements, the Consultants agreed to place at the disposal of the Company their judgment and expertise in the area of acute lung injury. In consideration for these services, the Company agreed to pay each consultant a non-refundable fee of \$5,000 per month, which shall accrue until such time as the Company raises at least \$2,000,000 in equity or debt financing, at which time such accrued amount will become due and payable. Pursuant to the Consulting Agreements, during the period from January 1, 2003 to December 31, 2003, the Company accrued \$120,000 in consulting fees. During the period from January 1, 2004 to December 31, 2004, the Company accrued an additional \$90,000 in consulting fees. The amounts due the Consultants at December 31, 2003 was \$125,000 and was included in accounts payable and accrued expenses.

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

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

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

#### Proprietary Rights Agreement

-----

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

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NOTE E - RELATED-PARTY TRANSACTIONS (CONTINUED)

Proprietary Rights Agreement (continued)

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

### Office Lease

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

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

### InOne Contract

-----

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

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

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

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

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NOTE F - NOTES PAYABLE

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

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

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

NOTE G - CAPITAL STOCK

The Company is authorized to issue 10,000,000 shares of preferred stock, par value \$.001 per share. No shares of preferred stock have been issued as of December 31, 2004. The company has authorized 100,000,000 shares of common stock, with a par value of \$.001 per share. In July, 2003 a one for twenty reverse stock split of the Company's common stock was effected. On April 6, 2004, the Company effected a 2 for 1 forward split of its common stock. Total authorized shares and par value remain the unchanged. Accordingly, the effect of the reverse and subsequent forward split has been presented in the accompanying financial statement and footnote disclosures. As of December 31, 2004, the Company has 62,423,388 shares of common stock issued and outstanding.

During the period ended December 31, 2002, the Company issued an aggregate of 1,459,188 shares of common stock to employees and consultants for services in the amount of \$ 9,782. All valuations of common stock issued for services were based upon the value of the services rendered, which did not differ materially from the fair value of the Company's common stock during the period the services were rendered. In addition, the Company issued 16,612,276 shares of common stock

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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

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### NOTE G - CAPITAL STOCK (CONTINUED)

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

During the year ended December 31, 2004, the Company issued an aggregate of 5,481,280 shares of common stock to consultants for services in the amount of \$2,877,872. All valuations of common stock issued for services were based upon the value of the services rendered, which did not differ materially from the fair value of the Company's common stock during the period the services were rendered. In addition, the Company issued 300,000 shares of common stock as with a fair value of \$36,000 as interest on a note payable. In addition, in conjunction with a private placement of stock (see below), the Company issued 6,855,062 shares of common stock in exchange for \$ 630,591 of previously incurred debt and accrued interest. In addition, the Company issued 590,000 shares of common stock in exchange for \$65,000 of previously issued debt. Total debt exchanged for stock during the year ended December 31, 2004 was \$695,591 of debt and interest for 7,745,062 shares of common stock. The Company also sold an aggregate of 18,160,000 shares of common stock in exchange for \$ 1,971,045 cash, net of costs and fees. The Company also sold 8,000 shares of common stock for \$1,200. The Company also issued an aggregate of 4,900,000 shares of common stock to its investment bankers as fees. The Company also issued 1,257,746 shares of common stock in settlement of \$157,219 of accounts payable. In addition, the Company issued an aggregate 1,440,000 shares of common stock to an officer and a director in satisfaction \$180,000 of liabilities.

#### Private Placement of Common Stock

-----

In October 2004, the Company completed a private placement of its common stock (the "Private Placement") whereby the Company sold an aggregate of \$2,450,000 worth of units (each a "Unit" and collectively, the "Units") to accredited investors (as defined by Rule 501 under the Securities Act of 1933, as amended) (the transaction is referred to herein as the "Private Placement"). The Company received proceeds of \$1,971,845 after costs of the issuance of \$298,155. Included in the \$2,450,000 sale was conversion of \$180,000 of accrued salary and consulting fees due to an officer and an director of the Company. The number of shares of common stock issued pursuant to the Private Placement was 19,600,000, along with warrants to purchase an additional 9,080,000 shares, plus warrants to

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purchase an additional 720,000 shares issued to the officer and director. The Company also issued an additional 4,900,000 shares of common stock to its investment banker as commission. The investment bankers did not acquire any warrants pursuant to this transaction.

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

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

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

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

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### NOTE G - CAPITAL STOCK

#### Private Placement of Common Stock (continued)

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

Also in October 2004, the Company entered into a settlement agreements with certain creditors whereby for full and complete satisfaction of claims totaling

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an aggregate of \$157,219 the Company issued Units with terms identical to those provided to investors in the Private Placement. The number of shares of common stock issued via these creditor conversions was 1,257,746, along with warrants to purchase an additional 628,873 shares.

### NOTE H - STOCK OPTIONS AND WARRANTS

#### Employee Stock Options

-----

The Company has adopted the 2003 Stock Option, Deferred Stock and Restricted Stock Plan (the "Plan") which authorizes the Board of Directors in accordance with the terms of the Plan, among other things, to grant incentive stock options, as defined by Section 422(b) of the Internal Revenue Code, nonstatutory stock options (collectively, the "Stock Options") and awards of restricted stock and deferred stock and to sell shares of common stock of the Company ("Common Stock") pursuant to the exercise of such stock options for up to an aggregate of 6,465,316 shares. The options will have a term not to exceed ten years from the date of the grant. There have been no options granted under this Plan.

Through December 31, 2002, GPN had granted pre-merger stock options to certain employees and consultants which are exercisable over various periods through March 2010. These stock options are currently held by the Company outside of the Plan.

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

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

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

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### NOTE H - STOCK OPTIONS AND WARRANTS (CONTINUED)

#### Employee Stock Options (continued)

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

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

Warrants

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

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

Transactions involving warrants are summarized as follows:

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

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Outstanding at December 31, 2004	17,666,210	\$ .49
	=====	=====

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NOTE H - STOCK OPTIONS AND WARRANTS (CONTINUED)

Warrants (continued)

-----

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

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

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

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

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

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

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

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

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months ended December 31, 2003, the Company recognized \$84,169 of expense in relation to these warrants. During the twelve months ended December 31, 2004, the remaining \$105,768 was charged to operations.

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

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

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NOTE H - STOCK OPTIONS AND WARRANTS (CONTINUED)

Warrants (continued)

-----

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

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

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

In October 2004, the Company issued a warrant to its president to purchase 448,980 shares (post-split) at a price of \$0.125 per share (post-split) as a

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performance bonus for achieving certain objectives. The Company valued this warrant using the Black-Scholes valuation model, and charged the amount of \$112,697 to operations during the twelve months ended December 31, 2004.

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

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

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

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

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

In April through June 2004, the Company issued warrants to purchase 77,500 shares (post-split) of its common stock at prices ranging from \$0.25 to \$2.00 per share (post-split) to certain investors as additional incentive under notes payable agreements. The Company valued these warrants using the Black-Scholes model, and charged the amount of \$17,915 to additional paid-in capital during the twelve months ended December 31, 2004.

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

### NOTE I - COMMITMENTS AND CONTINGENCIES

#### Office Leases

-----

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

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

### NOTE I - COMMITMENTS AND CONTINGENCIES (CONTINUED)

#### Employment and Consulting Agreements

-----

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

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

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

#### Litigation

-----

On December 13, 2001, service of process was effectuated upon GPN with regard to a fee agreement between GPN and Silver and Deboskey, a Professional Corporation located in Denver, Colorado. On November 27, 2002, judgment was entered in favor of Silver & Deboskey in the amount of \$28,091 and the amount of the judgment is included in accounts payable at December 31, 2004.

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

#### Obligation to Register Shares

-----

In October 2004, the Company sold shares of its common stock to investors in a private placement transaction. The Company is obligated to file a registration statement for the shares of common stock issued in the private placement and shares of common stock underlying the warrants issued in the private placement within 30 days of the final closing date of October 26, 2004, or November 25,

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

### NOTE J - INCOME TAXES

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

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

### NOTE J - INCOME TAXES (CONTINUED)

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

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

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

#### Non Current:

Net operating loss carryforward	\$ 2,400,000
Valuation allowance	(2,400,000)
	-----
Net deferred tax asset	\$ --
	=====

### NOTE K - LOSSES PER COMMON SHARE

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

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

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

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

NOTE L - SUBSEQUENT EVENTS

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

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IR BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY

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Condensed Consolidated Statement of Deficiency in  
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IR BioSciences Holdings, Inc. and Subsidiary  
(A Development Stage Company)  
Condensed Consolidated Balance Sheet as of September 30, 2005  
(Unaudited)

	Sept 30, 2005
	-----
Assets	
Current assets	
Cash and cash equivalents	\$ 667,041
Prepaid services and other current assets	15,713
	-----
Total current assets	682,754
Licensed proprietary rights, net	6,624
Furniture and equipment, net	4,795
	-----
Total assets	\$ 694,173
	=====
Liabilities and Deficiency in Stockholders' Equity	
Current liabilities	
Accounts payable and accrued liabilities	2,408,545
	-----
Total current liabilities	2,408,545
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 September 30, 2005	69,436
Additional paid-in capital	9,447,102
Deferred compensation	(14,859)



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Deficit Accumulated during the Development Stage	(11,216,051)
	-----
Total deficiency in stockholder's equity	(1,714,372)
	-----
Total liabilities and deficiency in stockholders' equity	\$ 694,173
	=====

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IR BioSciences Holdings, Inc. and Subsidiary  
 (A Development Stage Company)  
 Condensed Consolidated Statement of Operations  
 For the three and nine months ended September 30, 2005 and 2004,  
 And for the period of inception  
 (October 30, 2002) to September 30, 2005  
 (Unaudited)

	For the Three Months Ended Sept 30, 2005 -----	For the Three Months Ended Sept 30, 2004 -----	For the Nine Months Ended Sept 30, 2005 -----	For the Months Sept 200 -----
Revenues	--	--	--	
Operating expenses:				
Selling, general and administrative expenses	\$ 507,445	\$ 1,041,152	\$ 1,939,800	\$ 3,546
Merger fees and costs	--	--	--	
Financing cost	579,575	--	2,072,831	
	-----	-----	-----	-----
Total operating expenses	1,087,020	1,041,152	4,012,631	3,546
Operating loss	(1,087,020)	(1,041,152)	(4,012,631)	(3,546)
Other expense:				
Interest income (expense)	5,925	(70,612)	4,607	(506)
	-----	-----	-----	-----
Total other expense	5,925	(70,612)	4,607	(506)

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Loss before income taxes	(1,081,095)	(1,111,764)	(4,008,024)	(4,053,000)
Provision for income taxes	--	--	--	--
Net loss	<u>\$ (1,081,095)</u>	<u>\$ (1,111,764)</u>	<u>\$ (4,008,024)</u>	<u>\$ (4,053,000)</u>
Net loss per share - basic and diluted	\$ (0.02)	\$ (0.04)	\$ (0.06)	\$ (0.06)
Weighted average shares outstanding - basic and diluted	<u>69,337,210</u>	<u>29,040,133</u>	<u>67,103,634</u>	<u>27,129,000</u>

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IR Biosciences Holding, Inc. and Subsidiary  
(A Development Stage Company)  
Condensed Consolidated Statement of Deficiency in  
Stockholders' Equity For the period from inception  
(October 30, 2002) to September 30, 2005  
(unaudited)

	Common Stock		Additional	Deferred	Common
	Shares	Amount	Paid-In Capital	Compensation	Stock Subscrip
	-----	-----	-----	-----	-----
Balance at October 30, 2002 (date of inception)	--	\$ --	\$ --	--	\$ --
Shares of common stock issued at \$0.0006 per share to founders for license of proprietary right in December 2002	16,612,276	16,612	(7,362)	--	--
Shares of common stock issued at \$0.0006 per share to founders for services rendered in December 2002	1,405,310	1,405	(623)	--	--
Shares of common stock issued at \$0.1671 per share to consultants for services rendered in December 2002	53,878	54	8,946	(9,000)	--
Sale of common stock for cash at \$0.1671 per share in December 2002	185,578	186	30,815	--	--

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Net loss for the period from inception (October 30, 2002) to December 31, 2002	--	--	--	--
Balance at December 31, 2002 (reflective of stock splits)	18,257,042	18,257	31,776	(9,000)
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	--

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

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IR Biosciences Holding, Inc. and Subsidiary  
(A Development Stage Company)  
Condensed Consolidated Statement of Deficiency in Stockholders' Equity  
For the period from inception (October 30, 2002) to September 30, 2005  
(unaudited)

Common Stock	Additional Paid-In	Deferred	Common Stock
-----			

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	Shares	Amount	Capital	Compensation	Subscri
	-----	-----	-----	-----	-----
Beneficial conversion feature associated with notes issued in June 2003	--	--	60,560	--	
Amortization of deferred compensation	--	--	--	9,000	
Costs of GPN Merger in July 2003	2,368,130	2,368	(123,168)	--	
Value of warrants issued with extended notes payable in October 2003	--	--	189,937		
Value of Company warrants issued in conjunction with fourth quarter notes payable issued October through December 2003	--	--	207,457	--	
Value of warrants contributed by founders in conjunction with fourth quarter notes payable issued October through December 2003	--	--	183,543	--	
Value of warrants issued for services in October through December 2003	--	--	85,861	--	
Net loss for the twelve month period ended December 31, 2003	--	--	--	--	
	-----	-----	-----	-----	-----
Balance at December 31, 2003	23,431,300	23,431	1,035,441	--	
Shares granted at \$1.00 per share pursuant to the Senior Note Agreement in January 2004	600,000	600	599,400	(600,000)	
Shares issued at \$1.00 per share to a consultant for services rendered in January 2004	800,000	800	799,200	(800,000)	
Shares issued to a consultant at \$0.62 per share for services rendered in February 2004	40,000	40	24,760	(24,800)	
Shares issued to a consultant at \$0.40 per share for services rendered in March 2004	1,051,600	1,051	419,589	(420,640)	
Shares issued to a consultant at \$0.50 per share for services rendered in March 2004	500,000	500	249,500	(250,000)	
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					

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services rendered in March 2004	20,000	20	9,980	--
Shares issued to a consultant at \$0.40 per share for services rendered in March 2004	2,000	2	798	--
Shares issued to consultants at \$0.32 per share for services rendered in March 2004	91,600	92	29,220	--

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

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IR Biosciences Holding, Inc. and Subsidiary  
(A Development Stage Company)  
Condensed Consolidated Statement of Deficiency in Stockholders' Equity  
For the period from inception (October 30, 2002) to September 30, 2005  
(unaudited)

	Common Stock		Additional	Deferred	Common
	Shares	Amount	Paid-In Capital	Compensation	Stock Subscri
	-----	-----	-----	-----	-----
Shares to be issued to consultant at \$0.41 per share in April 2004 for services to be rendered through March 2005	--	--	--	(82,000)	
Shares granted pursuant to the New Senior Note Agreement in April 2004	600,000	600	149,400	(150,000)	
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	--	

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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	(500,000)
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	(25,000)
Shares issued to a consultant in July and September at \$0.41 per share for services to be rendered through April 2005	200,000	200	81,800	--
Shares issued to a consultant in September at \$0.12 to \$0.22 for services rendered through September 2004	127,276	127	16,782	--
Shares issued in July to September 2004 as interest on note payable	300,000	300	35,700	--
Issuance of warrants with notes payable in July and August 2004	--	--	72,252	--

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

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IR Biosciences Holding, Inc. and Subsidiary  
(A Development Stage Company) Condensed Consolidated Statement of  
Deficiency in Stockholders' Equity  
For the period from inception (October 30, 2002) to September 30, 2005  
(unaudited)

Common Stock		Additional	Deferred	Common
Shares	Amount	Paid-In Capital	Compensation	Stock Subscr
-----	-----	-----	-----	-----

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Accrued deferred compensation in August 2004 to a consultant for 100,000 shares at \$0.10 per share, committed but unissued	--	--	--	(10,000)
Shares issued in August 2004 at \$0.14 to a consultant for services to be performed through October 2004	100,000	100	13,900	(14,000)
Shares issued in August 2004 at \$0.125 per share for conversion of \$30,000 demand loan	240,000	240	29,760	--
Shares issued in August 2004 at \$0.16 per share to a consultant for services provided	125,000	125	19,875	--
Shares issued to employees at \$0.16 to \$0.25 per share	48,804	49	8,335	--
Commitment to issue 100,000 shares of stock to a consultant at \$0.23 per share for services to be provided through September 2005	--	--	--	(23,000)
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	--	--	112,697	--
Issuance of stock to investment bankers in October 2004 for commissions earned	4,900,000	4,900	(4,900)	--
Conversion of accounts payable to stock in October at \$0.125 per share	1,257,746	1,258	107,382	--
Value of warrants issued with accounts payable conversions	--	--	48,579	--
Conversion of demand loan to stock in October at \$0.11 per share	93,300	93	10,170	--
Forgiveness of notes payable in October 2004	--	--	36,785	--
Issuance of stock to officer and director at \$0.125 per share in October for conversion of liability	1,440,000	1,440	122,493	--
Value of warrants issued with officer and director conversion of liabilities	--	--	56,067	--

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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	--

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

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IR Biosciences Holding, Inc. and Subsidiary  
(A Development Stage Company)  
Condensed Consolidated Statement of Deficiency  
in Stockholders' Equity  
For the period from inception (October 30, 2002) to September 30, 2005  
(unaudited)

	Common Stock		Additional	Deferred	Common
	Shares	Amount	Paid-In Capital	Compensation	Stock Subscr
	-----	-----	-----	-----	-----
Issuance of warrants to note holders in October 2004	--	--	112,562	--	
Value of shares issued to CFO as compensation	100,000	100	34,900	--	
Value of warrants issued to members of advisory committees in in November and December	--	--	16,348	--	
Beneficial conversion feature associated with notes payable	--	--	124,709	--	
Shares issued in error to be cancelled	(9,002)	(9)	--	--	
Amortization of deferred compensation through December 31, 2004	--	--	--	2,729,454	
Loss for the twelve months ended December 31, 2004	--	--	--	--	
Balance at December 31, 2004	62,423,388	62,423	7,922,943	(169,986)	



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Sale of shares of common stock for cash at \$0.20 per share in March 2005 for warrant exercise, net of costs	6,600,778	6,601	1,184,256	--
Value of warrants issued to members of advisory committee in March 2005	--	--	137,049	--
Accrued deferred compensation in February, 2005 to a consultant for 50,000 shares at \$0.65 per share. Committed but unissued	--	--	--	(32,500)
Amortization of deferred compensation for the three months ended March 31, 2005	--	--	--	149,061
Warrants exercised at \$0.05 per share	80,000	80	3,920	--
Value of warrants issued to members of advisory committees in June 2005	--	--	70,781	--
Value of warrants issued to investors and service providers	--	--	32,991	--
Amortization of deferred compensation for the three months ended June 30, 2005	--	--	--	22,563
Conversion of notes payable into 232,153 common stock not yet issued	--	--	--	--
Issuance of 232,153 shares of common stock for conversion of notes payable	232,153	232	64,771	--
Issuance of 100,000 shares of common stock to consultant for services provided	100,000	100	9,900	--
Amortization of deferred compensation for the three months ended September 30, 2005	--	--	--	16,003
Value of warrants issued to advisory committee in September 2005 for services	--	--	20,491	--
Loss for the nine months ended September 30, 2005	--	--	--	--
Balance at September 30, 2005	69,436,319	69,436	9,447,102	(14,859)

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

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IR BioSciences Holdings, Inc. and Subsidiary  
(A Development Stage Company)  
Condensed Consolidated Statement of Cash Flows  
For the nine months ended September 30, 2005 and 2004,  
And for the period of inception  
(October 30, 2002) to September 30, 2005  
(Unaudited)

	For the Nine Months Ended September 30, 2005 -----	For the Nine Months Ended September 30, 2004 -----	Cumulat from In from In (Octobe 2002) t Septemb 2005 -----
Cash flows from operating activities:			
Net loss	\$ (4,008,024)	\$ (4,053,068)	\$ (11,21
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash compensation	462,773	2,636,280	3,86
Interest expense	4,007	74,517	15
Amortization of discount on notes payable	--	406,360	1,00
Depreciation and amortization	2,401	12,454	2
Changes in operating assets and liabilities:			
Prepaid services and other assets	(9,000)	33,543	(1
Accounts payable and accrued expenses	2,064,910	440,970	2,61
	-----	-----	-----
Net cash used in operating activities	(1,482,933)	(448,944)	(3,55
Cash flows from investing activities:			
Acquisition of property and equipment	--	--	(
	-----	-----	-----
Net cash used in investing activities	--	--	(
Cash flows from financing activities:			
Proceeds from notes payable	--	576,057	1,23
Principal payments on notes payable and demand loans	(14,997)	(174,000)	(26
Shares of stock sold for cash	1,190,857	31,200	3,25
Procees from exercised of warrants	4,000	--	
Officer repayment of amounts paid on his behalf	--	--	1
Cash paid on behalf of officer	--	--	(1
Cash paid on amount due to officer	--	--	
	-----	-----	-----
Net cash provided by financing activities	1,179,860	433,257	4,23
Net increase in cash and cash equivalents	(303,073)	(15,687)	66
Cash and cash equivalents at beginning of period	970,114	10,534	
	-----	-----	-----
Cash and cash equivalents at end of period	\$ 667,041	\$ (5,153)	\$ 66

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

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IR BioSciences Holdings, Inc. and Subsidiary  
 (A Development Stage Company)  
 Condensed Consolidated Statement of Cash Flows  
 For the nine months ended September 30, 2005 and 2004,  
 And for the period of inception  
 (October 30, 2002) to September 30, 2005  
 (Unaudited) (continued)

	For the Nine Months Ended September 30, 2005 -----	For the Nine Months Ended September 30, 2004 -----	Cumulat from In (Octobe 2002) t Septemb 2005 -----
Supplemental disclosure of cash flow information:			
Acquisition and capital restructure:			
Assets acquired	\$ --	\$ --	\$ --
Liabilities assumed	--	--	(120)
Common stock retained	--	--	(2)
Adjustment to additional paid-in capital	--	--	123
Organization costs	--	--	350
Total consideration paid	\$ --	\$ --	\$ 350
Cash paid during the period for:			
Interest	\$ 1,486	\$ 4,553	\$ 44
Taxes	\$ --	\$ --	\$ --
Common stock issued in exchange for proprietary rights	\$ --	\$ --	\$ 9,25
Common stock issued in exchange for services	\$ 10,000	\$ 2,095,240	\$ 2,925
Common stock issued in exchange for previously incurred debt and accrued interest	\$ 65,003	\$ 35,000	\$ 1,060
Common stock issued in exchange as interest	\$ --	\$ --	\$ 36

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Amortization of beneficial conversion feature	\$ --	\$ --	\$ 223
Stock options and warrants issued in exchange for services rendered	\$ 261,312	\$ --	\$ 762
Debt and accrued interest forgiveness from note holders	\$ --	\$ --	\$ 36
Common stock issued in satisfaction of accounts payable	\$ --	\$ 29,132	\$ 157
Common stock issued in satisfaction of amounts due to an Officer and a Director	\$ --	\$ --	\$ 180
Amortization of deferred compensation	\$ 187,627	\$ --	\$ 187
Fair value of common stock and warrants payable in connection with the filing of the registration statement.	\$ 2,072,831	\$ --	\$ 2,072

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

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IR BIOSCIENCES HOLDINGS, INC.  
(A DEVELOPMENT STAGE COMPANY)  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
September 30, 2005  
(Unaudited)

NOTE 1 - SUMMARY OF ACCOUNTING POLICIES

General

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The accompanying unaudited condensed financial statements have been prepared in accordance with the instructions to Form 10-QSB, and therefore, do not include all the information necessary for a fair presentation of financial position, results of operations and cash flows in conformity with accounting principles generally accepted in the United States of America for a complete set of financial statements.

In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. The results from operations for the nine-month periods ended September 30, 2005 and 2004 are not necessarily indicative of the results that may be expected for the year ended December 31, 2005. The unaudited condensed consolidated financial statements should be read in conjunction with the December 31, 2004 financial statements and footnotes thereto included in the Company's annual report on Form 10-KSB filed with the Securities and Exchange Commission on April 19, 2005 and form 10-KSB/A filed with the Securities and Exchange Commission on May 2, 2005.

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### Business and basis of presentation

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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 Homspera(TM), a proprietary compound that is derived from homeostatic substance P, a naturally occurring peptide. Currently, the majority of our development efforts are centered around two drug candidates derived from Homspera, Radilex(TM) and Viprovex(TM). Radilex has been formulated specifically for the indication of acute exposure to radiation. Viprovex was formulated specifically for applications relating to the treatment of maladies caused by exposure to various chemical and biological agents. Our research and development efforts are at a very early stage and Radilex and Viprovex have only undergone pre-clinical testing in mice. From its inception through the date of these financial statements, the Company has recognized no revenues and has incurred significant operating expenses.

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

### Reclassification

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Certain reclassifications have been made to conform to prior periods' data to the current presentation. These reclassifications had no effect on reported losses.

### Stock based compensation

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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 change 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, 2002 and for the subsequent periods.

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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:

Three months ended September 30, 2005:

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	2005 -----	2004 -----
Net loss, as reported	\$ (1,081,095)	\$ (1,111,764)
Compensation recognized under under APB 25	--	--
Compensation recognized under SFAS 123	77,969	--
	-----	-----
Pro forma net loss	\$ (1,159,064) =====	\$ (1,111,764) =====
Pro forma loss per share	\$ (0.02) =====	\$ (0.04) =====

Nine months ended September 30, 2005:

	2005 -----	2004 -----
Net loss, as reported	\$ (4,008,024)	\$ (4,053,068)
Compensation recognized under under APB 25	--	--
Compensation recognized under SFAS 123	77,969	--
	-----	-----
Pro forma net loss	\$ (4,085,993) =====	\$ (4,053,068) =====
Pro forma loss per share	\$ (0.06) =====	\$ (0.15) =====

Interim financial statements  
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The accompanying balance sheet as of September 30, 2005, the statements of operations for the three and nine months ended September 30, 2005 and 2004, and for the period of inception (October 30, 2002) to September 30, 2005, and the statements of cash flows for nine months ended September 30, 2005 and 2004, and from the period of inception (October 30, 2002) to September 30, 2005 are unaudited. These unaudited interim financial statements include all adjustments (consisting of normal recurring accruals), which, in the opinion of management, are necessary for a fair presentation of the results of operations for the periods presented. Interim results are not necessarily indicative of the results to be expected for a full year.

Use of estimates  
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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.

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### Long-lived assets

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

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### Prepaid services and other current assets

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Prepaid services and other current assets consist of (i) salary advance to an employee of \$2,300; (ii) deposits of \$2,260; and (iii) prepaid consulting and legal fees of \$11,153.

### Licensed proprietary rights

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The Company has licensed from its founders certain proprietary rights which the Company intends to utilize in the execution of its business plan. These proprietary rights are being amortized over the term of the license agreement, or ten years. The amount amortized during the three months ended September 30, 2005 and 2004 was \$232 during each period. The amount amortized during the nine months ended September 30, 2005 and 2004 was \$696 during each period. The Company amortized \$2,626 for the period from October 30, 2002 (inception) to September 30, 2005.

### Furniture and equipment

-----

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

Computer equipment	3 years
Furniture	7 years

The amounts depreciated for the three months ended September 30, 2005 and 2004 were \$967 and \$170, respectively. The amounts depreciated for the nine months ended September 30, 2005 and 2004 were \$1,705 and \$510, respectively. The amount depreciated from the date of inception (October 30, 2002) through September 30, 2005 was \$3,293.

### NOTE 2 - RELATED PARTY TRANSACTIONS

#### Proprietary rights agreements

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

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.

### Consulting agreements

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On December 16, 2002, the Company entered into consulting agreements (the "Consulting Agreements") with its two founders and chief research scientists (the "Consultants"). The Consulting Agreements were on a month-to-month basis. Under the terms of the Consulting Agreements, the Consultants agreed to place at the disposal of the Company their judgment and expertise in the area of acute lung injury. In consideration for these services, the Company agreed to pay each consultant a non-refundable fee of \$5,000 per month, which shall accrue until such time as the Company raises at least \$2,000,000 in equity or debt financing at which time such accrued amount will become due and payable. Pursuant to the Consulting Agreements, during the period from January 1, 2003 to December 31, 2003, the Company accrued \$120,000 in consulting fees. During the period from January 1, 2004 to December 31, 2004, the Company accrued an additional \$90,000 in consulting fees. The amounts due the Consultants at December 31, 2003 were \$125,000 and were included in accounts payable and accrued expenses.

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

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

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

During the three months ended September 30, 2005, the Company paid \$24,000 in consulting fees to the Consultant, and charged \$19,000 of this amount to operations and \$5,000 to prepaid consulting fees; During the three months ended



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September 30, 2004, the Company accrued the amount of \$15,000 in consulting fees payable to the Company's Founders. During the nine months ended September 30, 2005, the Company paid a total of \$62,000 to the Consultant, charging \$31,000 of this amount to operations and the remaining \$31,000 against the accrued liability; also during the nine months ended September 30, 2005, the Company accrued an additional \$19,000 in consulting fees due to the Consultant. At September 30, 2005, there is a prepaid asset of \$9,153 relating to these fees. During the nine months ended September 30, 2004, the Company accrued \$90,000 in consulting fees payable to the Consultants.

### Employment agreements

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 an annual salary of \$250,000. On August 10, 2005, we entered into a new employment agreement with our President and Chief Executive Officer, Michael K. Wilhelm. Pursuant to this new employment agreement we shall pay an annual salary of \$275,000 to Mr. Wilhelm through the term of his employment. Mr. Wilhelm's salary is payable in regular installments in accordance with the customary payroll practices of our company. Also on August 10, 2005, Mr. Wilhelm received an option to purchase 103,030 shares of the Company's stock at a price of \$0.33, which was 110% of the closing market price on the date of the option grant. These options vested on September 10, 2005. The Company valued these options using the intrinsic value method, and because the option price was less than the closing market price of the Company's common stock when the 103,030 options vested on August 10, 2005 there was no value assigned to these options.

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 our 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 three months ended September 30, 2005, the Company charged \$7,583 to operations for the issuance of 25,000 shares to Mr. Fermanis; for the nine months ended September 30, 2005, the Company charged to operations the amount of \$31,916 for the issuance of 75,000 shares to Mr. Fermanis.

### NOTE 3 - DEBT

During the nine months ended September 30, 2005, the Company paid two notes payable in the aggregate amount of \$80,000. Payment was made by cash in the amount of \$14,997, and by converting a note with a balance of \$65,003 into 232,153 shares of the Company's common stock at a price of \$0.28 per share. These shares were issued in July 2005.

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### NOTE 4 - EQUITY

Common stock

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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 5.)

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.

### Warrants

-----

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 three months ended March 31, 2005.

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. 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 three months ended June 30, 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. The Company valued these warrants using the Black-Scholes valuation model, and charged the amount of \$20,491 to operations during the three months ended September 30, 2005.

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

Warrants Outstanding			Warrants Exercisable		
Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighed Average Exercise Price	Number Exercisable	Weighted Remain Contractu (Yea

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\$0.01-0.10	519,780	3.64	\$0.01-0.10	519,780	3.64
0.125-0.21	903,919	3.72	0.125-0.21	903,919	3.72
0.25-0.56	9,270,406	3.82	0.25-0.56	9,270,406	3.82
1.00	830,844	2.29	1.00	830,844	2.29
2.00	49,050	3.49	2.00	49,050	3.49
	-----	-----		-----	-----
	11,573,999	3.69		11,573,999	3.69
	=====	=====		=====	=====

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Transactions involving warrants are summarized as follows:

	Number of Shares	Weighted Average Price Per Share
	-----	-----
Outstanding at January 1, 2005	17,666,210	\$ .49
Granted	268,033	.48
Exercised	(6,600,778)	.50
Canceled or expired	--	--
	-----	-----
Outstanding at March 31, 2005	11,333,465	\$ .47
Granted	366,814	.32
Exercised	(80,000)	.05
Cancelled or expired	(123,530)	2.00
	-----	-----
Outstanding at June 30, 2005	11,496,749	\$ .45
Granted	77,250	.56
Exercised	--	--
Cancelled or expired	--	--
	-----	-----
Outstanding at September 30, 2005	11,573,999	\$ .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
	----
Significant assumptions (weighted-average):	
Risk-free interest rate at grant date	3.69% to 4.00%
Expected stock price volatility	104% to 163%
Expected dividend payout	--
Expected option life-years (a)	3 to 5

Options

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We 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

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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.

During the nine months ended September 30, 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. The Company valued these options using the intrinsic value method. Since the exercise price of the options was greater than the market value of the Company's stock at the date of issuance, the Company assigned \$0 value to these options.

During the three months ended September 30, 2005, the Company issued options to an employee to purchase 103,030 shares of the Company's common stock at a price equal to 110% of the closing price of the Company's common stock on the date of issuance. The options have an exercise price of \$0.33 and a term of five years. The Company valued these options using the intrinsic value method. Since the exercise price of the options was greater than the market value of the Company's stock at the date of issuance, the Company assigned \$0 value to these options. The following table summarizes the changes in stock options outstanding and the related prices for the shares of the Company's common stock issued to employees of the Company.

Options Outstanding			Options Exercisable		
Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighed Average Exercise Price	Number Exercisable	Weighted Average Remaining Contractual Life (Years)
\$0.33	103,030	4.86	\$0.33	103,030	4.86
\$0.44	150,000	4.59	\$0.44	150,000	4.59
\$25.00	63,212	4.50	\$25.00	63,212	4.50
	-----	-----		-----	-----
	316,242	4.66		316,242	4.66
	=====	=====		=====	=====

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Transactions involving options are summarized as follows:

Number of Shares	Price Per Share	Weighted Average
	-----	-----
Outstanding at January 1, 2005	63,212	\$ 25.00
Granted	--	--
Exercised	--	--
Canceled or expired	--	--
	-----	-----
Outstanding at March 31, 2005	63,212	\$ 25.00
Granted	--	--

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Exercised	--	--
Cancelled or expired	--	--
	-----	-----
Outstanding at June 30, 2005	63,212	\$ 25.00
Granted	253,030	\$ 0.40
Exercised	--	--
Cancelled or expired	--	--
	-----	-----
Outstanding at September 30, 2005	316,242	\$ 5.31
	=====	=====

Shares and warrants issuable due to late filing of registration statement

-----

In October 2004, the Company completed a private placement sale of shares of its common stock and warrants to purchase additional shares of common stock. The Company agreed to register these shares along with the shares underlying these warrants within ninety days from the closing date of the transaction, or the Company would incur a penalty equivalent to an additional 2% of the shares and warrants to be registered for every 30 days that the Company fails 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 September 30, 2005, the Company is required to issue additional 3,827,960 shares of common stock and warrants to purchase an additional 1,507,280 shares of common stock. These shares have been valued at the market price of the common stock at the time each 30 day period, for a total of \$1,539,331 at September 30, 2005; the warrants have been valued at \$533,500 at September 30, 2005 utilizing the Black-Scholes valuation model. The total value of the common stock and warrants issuable pursuant to this late filing penalty at September 30, 2005 is \$2,072,831. This amount was charged to finance cost during the nine months ended September 30, 2005 and are included in the Company's balance sheet at September 30, 2005 as accounts payable and accrued liabilities.

The Company anticipates completing the registration of these shares during the quarter ended December 31, 2005, but expects that an obligation to issue approximately 1,245,240 additional shares and 490,320 additional warrants at an aggregate cost of approximately \$649,367 will be incurred.

#### NOTE 5 - SUBSEQUENT EVENTS

None.

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### PART II

#### INFORMATION NOT REQUIRED IN PROSPECTUS

#### ITEM 24 INDEMNIFICATION OF DIRECTORS AND OFFICERS

Under Section 145 of the General Corporation Law of the State of Delaware, we can indemnify our directors and officers against liabilities they may incur in such capacities, including liabilities under the Securities Act of 1933, as amended (the "Securities Act"). Our certificate of incorporation provides that, pursuant to Delaware law, our directors shall not be liable for monetary damages for breach of the directors' fiduciary duty of care to us and our stockholders. This provision in the certificate of incorporation does not eliminate the duty of care, and in appropriate circumstances equitable remedies

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such as injunctive or other forms of nonmonetary relief will remain available under Delaware law. In addition, each director will continue to be subject to liability for breach of the director's duty of loyalty to us or our stockholders, for acts or omissions not in good faith or involving intentional misconduct or knowing violations of the law, for actions leading to improper personal benefit to the director, and for payment of dividends or approval of stock repurchases or redemptions that are unlawful under Delaware law. The provision also does not affect a director's responsibilities under any other law, such as the federal securities laws or state or federal environmental laws.

Our bylaws provide for the indemnification of our directors to the fullest extent permitted by the Delaware General Corporation Law. Our bylaws further provide that our Board of Directors has sole discretion to indemnify our officers and other employees. We may limit the extent of such indemnification by individual contracts with our directors and executive officers, but have not done so. We are required to advance, prior to the final disposition of any proceeding, promptly on request, all expenses incurred by any director or executive officer in connection with that proceeding on receipt of an undertaking by or on behalf of that director or executive officer to repay those amounts if it should be determined ultimately that he or she is not entitled to be indemnified under our bylaws or otherwise. We are not, however, required to advance any expenses in connection with any proceeding if a determination is reasonably and promptly made by our Board of Directors by a majority vote of a quorum of disinterested Board members that (a) the party seeking an advance acted in bad faith or deliberately breached his or her duty to us or our stockholders and (b) as a result of such actions by the party seeking an advance, it is more likely than not that it will ultimately be determined that such party is not entitled to indemnification pursuant to the applicable sections of our bylaws.

We also have directors' and officers' liability insurance.

### ITEM 25 OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, if any, payable by the Registrant relating to the sale of common stock being registered. All amounts are estimates except the SEC registration fee.

SEC registration fee .....	\$ 1,613
Printing and engraving expenses .....	5,000
Legal fees and expenses .....	85,000
Accounting fees and expenses .....	50,000
Transfer agent and registrar's fees and expenses .....	2,000
Miscellaneous expenses .....	6,387
	-----
Total.....	\$150,000
	=====

The Registrant has agreed to bear expenses incurred by the selling stockholders, up to a maximum limit of \$15,000, that relate to the registration of the shares of common stock being offered and sold by the selling stockholders. All such expenses in excess of \$15,000 will be borne by the selling stockholders in proportion to the number of shares being registered by each stockholder.

### ITEM 26 RECENT SALES OF UNREGISTERED SECURITIES

During the last three years, we have issued unregistered securities to the persons, as described below. None of these transactions involved any underwriters, underwriting discounts or commissions, except as specified below, or any public offering, and we believe that each transaction was exempt from the

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registration requirements of the Securities Act of 1933 by virtue of Section 4(2) thereof and/or Regulation D promulgated thereunder. All recipients had adequate access, through their relationships with us, to information about us.

In January 2002, we sold to Todd M. Ficeto, who was the sole director and officer of GPN Network, Inc., 2,500,000 units at \$0.06 per unit for an aggregate purchase price of \$150,000. Each unit sold included two shares of our common stock and one five-year warrant to purchase one share of our common stock at \$0.03 per share. The sale of the units resulted in the issuance of 5,000,000 shares of our common stock and warrants exercisable for an additional 2,500,000 shares of our common stock. The securities were offered and sold in reliance upon exemption from

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registration pursuant to Section 4(2) of the Securities Act and Rule 506 promulgated thereunder.

On January 20, 2003, the Company entered into a \$15,000 Convertible Promissory Note bearing 8% interest per month with an accredited individual investor. The principal on the note was subsequently repaid. On March 31, 2005 in accordance with the terms of the Promissory Note, accrued interest of \$2,410.96 was converted into 19,288 shares of our common stock releasing the Company from any further obligation under the Note. These shares have been accrued pending issuance. No general solicitation or advertising was undertaken in connection with the offer and sale of the Note and the shares. The investor represented to the Company that the investor was purchasing the securities for the investor's own account and not with a present view towards the distribution thereof. In addition, each investor acknowledged and agreed that the note and the shares had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On June 11, 2003, the Company entered into a \$50,000 Convertible Promissory Note bearing 10% interest for a term of 120 days to an individual accredited investor. The term was extended to October 16, 2004, the closing date of the Private Placement (see below). Immediately upon the closing of the Private Placement, and in accordance with the terms of the Promissory Note, all outstanding principal and accrued interest converted into 746,108 shares of our common stock along with five-year warrants to purchase an additional 373,054 shares of common stock at \$.50 per share releasing the Company from any further obligation under the Note. No general solicitation or advertising was undertaken in connection with the offer and sale of the Note. The investor represented to the Company that the investor was purchasing the Note for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the Note and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On June 11, 2003, the Company entered into a \$50,000 Convertible Promissory Note bearing 10% interest for a term of 120 days to an individual accredited investor. The term was extended to October 16, 2004, the closing date of the Private Placement. Immediately upon the closing of the Private Placement,

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and in accordance with the terms of the Promissory Note, all outstanding principal and accrued interest converted into 745,225 shares of our common stock along with five-year warrants to purchase an additional 372,613 shares of common stock at \$.50 per share releasing the Company from any further obligation under the Note. No general solicitation or advertising was undertaken in connection with the offer and sale of the Note. The investor represented to the Company that the investor was purchasing the Note for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the Note and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On June 13, 2003, the Company entered into a \$100,000 Convertible Promissory Note bearing 10% interest for a term of 180 days to an individual accredited investor. The term was extended to October 16, 2004, the closing date of the Private Placement. Immediately upon the closing of the Private Placement, and in accordance with the terms of the Promissory Note, 50% of the outstanding principal was paid back in cash and 50% of the principal and accrued interest converted into 614,680 shares of our common stock along with five-year warrants to purchase an additional 307,340 shares of common stock at \$.50 per share releasing the Company from any further obligation under the Note. No general solicitation or advertising was undertaken in connection with the offer and sale of the Note. The investor represented to the Company that the investor was purchasing the Note for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the Note and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On June 16, 2003, the Company entered into a \$20,000 Convertible Promissory Note bearing 10% interest for a term of 120 days to an individual accredited investor. The term was extended to October 16, 2004, the closing date of the Private Placement. Immediately upon the closing of the Private Placement, and in accordance with the terms of the Promissory Note, all outstanding principal and accrued interest converted into 297,722 shares of our common stock along with five-year warrants to purchase an additional 148,861 shares of common stock at \$.50 per share releasing the Company from any further obligation under the Note. No general solicitation or advertising was undertaken in connection with the offer and sale of the Note. The investor represented to the Company that the

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investor was purchasing the Note for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the Note and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.



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On July 20, 2003, we entered into and consummated an agreement and plan of merger, pursuant to which we acquired ImmuneRegen BioSciences, Inc ("ImmuneRegen") in a reverse merger, which resulted in the issuance of 2,368,130 shares of our common stock. Pursuant to the terms of the merger, the stockholders of ImmuneRegen were issued shares of our common stock exchange for their shares in ImmuneRegen. The securities were issued to less than 35 purchasers and in reliance upon exemption from registration pursuant to Section 4(2) of the Securities Act and Rule 506 promulgated thereunder. No general solicitation or advertising was undertaken in connection with the offer and sale of the securities. The stockholders were also provided with access to our SEC filings, including the Company's annual reports on Form 10-KSB and its quarterly reports on Form 10-QSB.

In May and June 2003, ImmuneRegen BioSciences, Inc. had sold and issued eight secured convertible promissory notes in the aggregate principal amount of \$495,000 that were due 120 days from the date of issuance. When the notes were due, three were paid and five were exchanged for 8% amended secured convertible notes ("Amended Notes") in the aggregate principal amount of \$245,000 in October 2003. The five accredited investors who received the Amended Notes were also issued five-year warrants to purchase a total of 245,000 shares of our common stock at an exercise price of \$1.00 per share. The securities were offered and sold in reliance upon exemption from registration pursuant to Section 4(2) of the Securities Act and Rule 506 promulgated thereunder. No general solicitation or advertising was undertaken in connection with the offer and sale of the securities. Each investor represented to the Company that the investor was purchasing the securities for the investor's own account and not with a present view towards the distribution thereof. In addition, each investor acknowledged and agreed that the securities and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements.

On September 9, 2003, the Company entered into a \$25,000 Convertible Promissory Note bearing 8% interest for a term of 180 days to an individual accredited investor. The term was extended to October 16, 2004, the closing date of the Private Placement. Immediately upon the closing of the Private Placement, and in accordance with the terms of the Promissory Note, all outstanding principal and accrued interest converted into 272,711 shares of our common stock along with five-year warrants to purchase an additional 136,356 shares of common stock at \$.50 per share releasing the Company from any further obligation under the Note. No general solicitation or advertising was undertaken in connection with the offer and sale of the Note. The investor represented to the Company that the investor was purchasing the Note for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the Note and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On September 9, 2003, the Company entered into a \$25,000 Convertible Promissory Note bearing 8% interest for a term of 180 days to an individual accredited investor. The term was extended to October 16, 2004, the closing date of the Private Placement. Immediately upon the closing of the Private Placement, and in accordance with the terms of the Promissory Note, all outstanding principal and accrued interest converted into 371,847 shares of our common stock along with five-year warrants to purchase an additional 185,924 shares of common stock at \$.50 per share releasing the Company from any further obligation under the Note. No general solicitation or advertising was undertaken in connection

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with the offer and sale of the Note. The investor represented to the Company that the investor was purchasing the Note for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the Note and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On September 23, 2003, the Company entered into a \$125,000 Convertible Promissory Note bearing 8% interest for a term of 180 days to an individual accredited investor. The term was extended to October 16, 2004, the closing date of the Private Placement. Immediately upon the closing of the Private Placement, and in accordance with the terms of the Promissory Note, all outstanding principal and accrued interest converted into 1,359,511 shares of our common stock along with five-year warrants to purchase an additional 679,756 shares of common stock at \$.50

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per share releasing the Company from any further obligation under the Note. No general solicitation or advertising was undertaken in connection with the offer and sale of the Note. The investor represented to the Company that the investor was purchasing the Note for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the Note and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On September 25, 2003, the Company entered into a \$25,000 Convertible Promissory Note bearing 8% interest for a term of 180 days to an individual accredited investor. The term was extended to October 16, 2004, the closing date of the Private Placement. Immediately upon the closing of the Private Placement, and in accordance with the terms of the Promissory Note, all outstanding principal and accrued interest converted into 271,787 shares of our common stock along with five-year warrants to purchase an additional 135,894 shares of common stock at \$.50 per share releasing the Company from any further obligation under the Note. No general solicitation or advertising was undertaken in connection with the offer and sale of the Note. The investor represented to the Company that the investor was purchasing the Note for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the Note and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On September 26, 2003, the Company entered into a \$30,000 Convertible Promissory Note bearing 8% interest per month with the father of one of our Directors. The principal on the note was subsequently repaid. On January 28, 2005 in accordance with the terms of the Promissory Note, accrued interest of \$2,040.55 was converted into 27,207 shares of our common stock releasing the

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Company from any further obligation under the Note. These shares have been accrued pending issuance. No general solicitation or advertising was undertaken in connection with the offer and sale of the Note. The investor represented to the Company that the investor was purchasing the Note for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the Note and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On September 29, 2003, the Company entered into a \$25,000 Convertible Promissory Note bearing 8% interest for a term of 180 days to an individual accredited investor. The term was extended to October 16, 2004, the closing date of the Private Placement. Immediately upon the closing of the Private Placement, and in accordance with the terms of the Promissory Note, all outstanding principal and accrued interest converted into 271,556 shares of our common stock along with five-year warrants to purchase an additional 135,778 shares of common stock at \$.50 per share releasing the Company from any further obligation under the Note. No general solicitation or advertising was undertaken in connection with the offer and sale of the Note. The investor represented to the Company that the investor was purchasing the Note for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the Note and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

In October through December 2003, we sold and issued ten 8% secured convertible promissory notes ("Fourth Quarter Notes") in the aggregate principal amount of \$391,000 that were due 180 days from the date of issuance. The ten accredited investors who received the Fourth Quarter Notes were also issued five-year warrants to purchase a total of 391,000 shares of our common stock at an exercise price of \$1.00 per share. The securities were offered and sold in reliance upon exemption from registration pursuant to Section 4(2) of the Securities Act and Rule 506 promulgated thereunder. No general solicitation or advertising was undertaken in connection with the offer and sale of the Fourth Quarter Notes. Each investor represented to the Company that the investor was purchasing the Fourth Quarter Notes for the investor's own account and not with a present view towards the distribution thereof. In addition, each investor acknowledged and agreed that the Fourth Quarter Notes and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements.

In October 2003 through December 2003, we issued, in exchange for accounting, marketing, business consulting, investor relations and public relations services valued at approximately \$85,861, five-year warrants to eight

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investors for the purchase of an aggregate of 169,572 shares of our common stock at exercise prices ranging from \$0.25 to \$2.00 per share. The securities were offered and sold in reliance upon exemption from registration pursuant to Section 4(2) of the Securities Act and Rule 506 promulgated thereunder. The

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investors were financially able to bear the economic risk of the investment and capable of evaluating the merits and risks of the acquisition of the securities. Each investor also had received and reviewed all information necessary or appropriate for deciding whether to purchase the securities, including the Company's periodic SEC reports. No general solicitation or advertising was undertaken in connection with the offer and sale of the securities. Each investor represented to the Company that the investor was purchasing the securities for the investor's own account and not with a present view towards the distribution thereof. In addition, each investor acknowledged and agreed that the securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements.

On November 10, 2003, the Company entered into a \$50,000 Convertible Promissory Note bearing 8% interest for a term of 180 days to an individual accredited investor. The term was extended to October 16, 2004, the closing date of the Private Placement. Immediately upon the closing of the Private Placement, and in accordance with the terms of the Promissory Note, all outstanding principal and accrued interest converted into 538,374 shares of our common stock along with five-year warrants to purchase an additional 269,187 shares of common stock at \$.50 per share releasing the Company from any further obligation under the Note. No general solicitation or advertising was undertaken in connection with the offer and sale of the Note. The investor represented to the Company that the investor was purchasing the Note for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the Note and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On November 18, 2003, the Company entered into a \$16,000 Convertible Promissory Note bearing 8% interest for a term of 220 days to an individual accredited investor. The term was extended to October 16, 2004, the closing date of the Private Placement. Immediately upon the closing of the Private Placement, and in accordance with the terms of the Promissory Note, \$5,000 of the outstanding principal was paid back in cash and the remaining \$11,000 of the principal plus accrued interest converted into 129,886 shares of our common stock along with five-year warrants to purchase an additional 64,943 shares of common stock at \$.50 per share releasing the Company from any further obligation under the Note. No general solicitation or advertising was undertaken in connection with the offer and sale of the Note. The investor represented to the Company that the investor was purchasing the Note for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the Note and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On December 12, 2003, the Company entered into a \$20,000 Convertible Promissory Note bearing 8% interest per month with an accredited investor, the mother-in-law Of our Chief Executive Officer. The principal on the note was subsequently repaid. On October 15, 2004 in accordance with the terms of the Promissory Note, accrued interest of \$1,354.52 was converted into 13,454 shares of our common stock releasing the Company from any further obligation under the Note. These shares have been accrued pending issuance. No general solicitation or advertising was undertaken in connection with the offer and sale of the

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securities. The investor represented to the Company that the investor was purchasing the securities for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

In January 2004, we entered into a 12% senior secured promissory note ("Senior Note") that had a term of 90 days. As an additional incentive to enter into the Senior Note, we issued 600,000 shares of our common stock to the note holder, and such shares were valued at \$600,000. In April 2004, the Senior Note was paid and we entered into a new 12% senior secured promissory note ("New Senior Note") that had a term of 90 days. As an additional incentive to enter into the New Senior Note, we issued another 600,000 shares of our common stock to the note holder, and such shares were also valued at \$600,000. The note holders were financially able to bear the economic risk of the investment and capable of evaluating the merits and risks of the acquisition of the securities. Each note holder also had received and reviewed all information necessary or appropriate for deciding whether to purchase the securities, including the Company's periodic SEC reports. No general solicitation or advertising was undertaken in connection with the offer and sale of the shares. The note holder represented to the Company that the note holder was purchasing the securities

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for the note holder's own account and not with a present view towards the distribution thereof. In addition, the note holder acknowledged and agreed that the shares had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the shares were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

In February 2004, we issued 40,000 shares of our common stock at \$0.62 per share to a consultant that is an accredited investor in exchange for public relations services to be provided through August 2004. The services were valued at approximately \$24,800. No general solicitation or advertising was undertaken in connection with the offer and sale of the shares. The consultant represented to the Company that the consultant was purchasing the securities for the consultant's own account and not with a present view towards the distribution thereof. In addition, the consultant acknowledged and agreed that the shares had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the shares were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

In March 2004, we sold and issued 8,000 shares of our common stock at \$0.15 per share for an aggregate purchase price of \$1,200 to an investor. The investor was financially able to bear the economic risk of the investment and capable of evaluating the merits and risks of the acquisition of the securities. The investor also had received and reviewed all information necessary or appropriate for deciding whether to purchase the securities, including the Company's periodic SEC reports. No general solicitation or advertising was undertaken in connection with the offer and sale of the shares. Each investor

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represented to the Company that the investor was purchasing the securities for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the shares had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the shares were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

In May 2004 we also issued 350,000 shares of our common stock to a note holder upon conversion of a note payable in the principal amount of \$35,000 plus accrued interest. No general solicitation or advertising was undertaken in connection with the offer and sale of the shares. The note holder represented to the Company that the he was acquiring the shares for the his own account and not with a present view towards the distribution thereof. In addition, the note holder acknowledged and agreed that the shares had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the shares were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

In April 2004 extended a 90 day offer to purchase certain rights to our patents for Homspera for \$30,000 to an accredited investor. On August 17, 2004, at the conclusion of the 90-day period, if not exercised, the option would convert into common shares of stock and warrants. In accordance with the terms of the option, upon expiration the \$30,000 was converted into 240,000 shares of our common stock along with five-year warrants to purchase an additional 120,000 shares of common stock at \$.50 per share. No general solicitation or advertising was undertaken in connection with the offer and sale of the securities. The investor represented to the Company that the he was acquiring the shares for the his own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On May 6, 2004, the Company entered into a \$2,500 Convertible Promissory Note bearing 12% interest for a term of 160 days to an individual accredited investor. The term was extended to October 16, 2004, the closing date of the Private Placement. Immediately upon the closing of the Private Placement, and in accordance with the terms of the Promissory Note, all outstanding principal and accrued interest converted into 26,608 shares of our common stock along with five-year warrants to purchase an additional 13,304 shares of common stock at \$.50 per share releasing the Company from any further obligation under the Note. No general solicitation or advertising was undertaken in connection with the offer and sale of the Note. The investor represented to the Company that the investor was purchasing the Note for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the Note and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to

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Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On May 14, 2004, the Company entered into a \$75,000 Convertible Promissory Note bearing 12% interest for a term of 160 days to an individual accredited investor. The term was extended to October 16, 2004, the closing date of the Private Placement. Immediately upon the closing of the Private Placement, and in accordance with the terms of the Promissory Note, all outstanding principal and accrued interest converted into 788,750 shares of our common stock along with five-year warrants to purchase an additional 394,375 shares of common stock at \$.50 per share releasing the Company from any further obligation under the Note. No general solicitation or advertising was undertaken in connection with the offer and sale of the Note. The investor represented to the Company that the investor was purchasing the Note for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the Note and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

In May 2004, we issued five-year warrants to purchase 500,000 shares of our common stock at an exercise price of \$0.25 per share to each of one of our founders and our Chief Executive Officer, Michael Wilhelm. The securities were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

In May 2004 we also issued 125,000 shares of our common stock at \$0.20 per share to a consultant as a due diligence fee. The consultant was financially able to bear the economic risk of the investment and capable of evaluating the merits and risks of the acquisition of the shares. The consultant also had received and reviewed all information necessary or appropriate for deciding whether to purchase the shares, including the Company's periodic SEC reports. No general solicitation or advertising was undertaken in connection with the offer and sale of the shares. The consultant represented to the Company that the consultant was purchasing the securities for the consultant's own account and not with a present view towards the distribution thereof. In addition, the consultant acknowledged and agreed that the shares had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the shares were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

In May 2004 we also issued 500,000 shares of our common stock to a consultant in exchange for business consulting services to be provided through December 2004, and the stock price of \$1.00 per share was determined as of the date that we entered into the related consulting agreement in December 2003. The consultant was financially able to bear the economic risk of the investment and capable of evaluating the merits and risks of the acquisition of the shares. The consultant also had received and reviewed all information necessary or appropriate for deciding whether to purchase the shares, including the Company's periodic SEC reports. No general solicitation or advertising was undertaken in connection with the offer and sale of the shares. The consultant represented to the Company that the consultant was purchasing the securities for the

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consultant's own account and not with a present view towards the distribution thereof. In addition, the consultant acknowledged and agreed that the shares had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the shares were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On June 18, 2004, the Company entered into a \$10,000 Convertible Promissory Note bearing 8% interest for a term of 120 days to an individual accredited investor. The term was extended to October 16, 2004, the closing date of the Private Placement. Immediately upon the closing of the Private Placement, and in accordance with the terms of the Promissory Note, all outstanding principal and accrued interest converted into 136,919 shares of our common stock along with five-year warrants to purchase an additional 68,460 shares of common stock at \$.50 per share releasing the Company from any further obligation under the Note. No general solicitation or advertising was undertaken in connection with the offer and sale of the Note. The investor represented to the Company that the investor was purchasing the Note for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the Note and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

In July 2004, we issued 250,000 shares of common stock at \$0.10 per share to an accredited entity in exchange for Investor and Public Relations services to be provided through July, 2005. The services were valued at approximately \$25,000. No general solicitation or advertising was

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undertaken in connection with the offer and sale of the shares. The consultant represented to the Company that the consultant was purchasing the securities for the consultant's own account and not with a present view towards the distribution thereof. In addition, the consultant acknowledged and agreed that the shares had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from registration requirements. Therefore, the Company believes that the shares were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities act of 1933, as amended, and Rule 506 promulgated thereunder.

In August 2004, we issued 100,000 shares of common stock at \$0.14 per share to an accredited consultant in exchange for Strategic Planning services to be provided through October 2004. The services were valued at approximately \$14,000. No general solicitation or advertising was undertaken in connection with the offer and sale of the shares. The consultant represented to the Company that the consultant was purchasing the securities for the consultant's own account and not with a present view towards the distribution thereof. In addition, the consultant acknowledged and agreed that the shares had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from registration requirements. Therefore, the Company believes that



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the shares were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities act of 1933, as amended, and Rule 506 promulgated thereunder.

In July and September of 2004, we issued a total of 200,000 shares of common stock at \$0.41 per share to an accredited consultant in exchange for financial consulting services to be provided through April 2005. The services were valued at approximately \$82,000. No general solicitation or advertising was undertaken in connection with the offer and sale of the shares. The consultant represented to the Company that the consultant was purchasing the securities for the consultant's own account and not with a present view towards the distribution thereof. In addition, the consultant acknowledged and agreed that the shares had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from registration requirements. Therefore, the Company believes that the shares were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities act of 1933, as amended, and Rule 506 promulgated thereunder.

On August 16, 2004, the Company entered into a \$15,000 Convertible Promissory Note bearing \$500 interest per month for a term of 30 days to an individual accredited investor. The term was extended to October 16, 2004, the closing date of the Private Placement. Immediately upon the closing of the Private Placement, and in accordance with the terms of the Promissory Note, all outstanding principal and accrued interest converted into 131,467 shares of our common stock along with five-year warrants to purchase an additional 65,734 shares of common stock at \$.50 per share releasing the Company from any further obligation under the Note. No general solicitation or advertising was undertaken in connection with the offer and sale of the Note. The investor represented to the Company that the investor was purchasing the Note for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the Note and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On August 23, 2004, the Company entered into a \$5,000 Convertible Promissory Note bearing 8% interest per month to an individual accredited investor. On October 26, 2004 in accordance with the terms of the Promissory Note, principal of \$5,000 and accrued interest of \$71 was converted into 67,613 shares of our common stock releasing the Company from any further obligation under the Note. These shares have been accrued pending issuance. No general solicitation or advertising was undertaken in connection with the offer and sale of the Note. The investor represented to the Company that the investor was purchasing the Note for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the Note and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

In September 2004, we issued 127,276 shares of common stock at \$0.12 - \$0.22 per share to an accredited consultant in exchange for financial consulting services provided through September 2004. The services were valued at approximately \$16,909. No general solicitation or advertising was undertaken in connection with the offer and sale of the shares. The consultant represented to

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the Company that the consultant was purchasing the securities for the consultant's own account and not with a present view towards the distribution thereof. In addition, the consultant acknowledged and agreed that the shares had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from registration requirements. Therefore, the Company believes that the shares were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities act of 1933, as amended, and Rule 506 promulgated thereunder

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In October 2004, we completed a private placement, whereby we sold an aggregate of \$2,450,000 worth of units to accredited investors (the "Private Placement"). Each unit was sold for \$10,000 (the "Unit Price") and consisted of (a) a number of shares of our common stock determined by dividing the Unit Price by \$0.125, and (b) a warrant to purchase, at any time prior to the fifth anniversary following the date of issuance of the warrant, a number of shares of our common stock equal to fifty percent (50%) of the number of shares included within the unit, at a price equal to \$0.50 per share of common stock. Thus, each unit consisted of 80,000 shares of our common stock and a five-year warrant to purchase an additional 40,000 shares of our common stock at an exercise price of \$0.50 per share. We issued an aggregate 27,560,897 shares of our common stock and warrants to purchase 13,780,449 shares of our common stock in the Private Placement. In consideration of the investment, we granted to each investor certain registration rights and anti-dilution rights. The registration rights provide, if the Registration Statement is not effective as of 90-days following the second closing date (October 26, 2004), we must issue to the holders of units sold in the Private Offering an additional 2% of their securities each month. To date we are obligated to issue an aggregate of 3,228,400 shares and 1,271,200 warrants pursuant to this penalty provision. No general solicitation or advertising was undertaken in connection with the offer and sale of the Units. The investors each represented to the Company that the investor was purchasing Units for the his or her own account and not with a present view towards the distribution thereof. In addition, each investor acknowledged and agreed that the Units and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. The securities were offered and sold in reliance upon exemption from registration pursuant to Section 4(2) of the Securities Act and Rule 506 promulgated thereunder.

Further to the Private Placement, on October 26, 2004 we entered into a settlement agreement with 8 accredited creditors whereby for full and complete satisfaction of claims totaling an aggregate of \$157,218 (the "Claim Amount"), we issued to the creditors the following: (a) a number of shares of our common stock determined by dividing the Claim Amount by \$0.125, and (b) warrants to purchase, at any time prior to the fifth anniversary following the date of issuance of the warrant, a number of shares of our common stock equal to fifty percent (50%) of the number of shares described above, at a price equal to \$0.50 per share of common stock. The warrants are identical to the warrants issued in the Private Placement. No general solicitation or advertising was undertaken in connection with the offer and sale of the securities. The investors each represented to the Company that the investor was acquiring the securities for the his or her own account and not with a present view towards the distribution thereof. In addition, each investor acknowledged and agreed that the securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. The securities were offered and sold in reliance upon exemption from registration pursuant to Section 4(2) of

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the Securities Act and Rule 506 promulgated thereunder.

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. There were 98 accredited investors who purchased units in the Private Placement. The securities were offered and sold in reliance upon exemption from registration pursuant to Section 4(2) of the Securities Act and Rule 506 promulgated thereunder.

In September 2004 we entered into a settlement agreement with one of our Directors, Theodore Staahl, whereby for full and complete satisfaction of claims totaling \$10,263.01, we issued to our Director 93,300 shares of our common stock, determined by dividing the amount owed by \$0.11. Under the terms of the settlement agreement, our Director released us from all claims, known or unknown, relating to the amount owed. The securities were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder. The Director qualified as an accredited investor (as defined by Rule 501 under the Securities Act of 1933, as amended).

On November 18, 2004 we issued warrants to a member of our Bioterrorism Preparedness Advisory Board to purchase, at any time prior to the third anniversary following the date of issuance of the warrant, a number of shares of our common stock equal to 50,000, at a price equal to \$0.125 per share of common stock for advice on logistics, introductions to various organizations and attendance of meetings. No general solicitation or advertising was undertaken in connection with the offer and sale of the securities. The investor acknowledged and agreed that the securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. The securities were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder. The investor qualified as an accredited investor (as defined by Rule 501 under the Securities Act of 1933, as amended).

On December 16, 2004 we issued warrants to a member of our Oncology and Dermatology Advisory Board to purchase, at any time prior to the third anniversary following the date of issuance of the warrant, a number of shares of our common stock equal to 10,000, at a price equal to \$0.50 per share of common

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stock for advice on potential oncology applications for Homspera. No general solicitation or advertising was undertaken in connection with the offer and sale of the securities. The investor acknowledged and agreed that the securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. The securities were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder. The investor qualified as an accredited investor (as defined by Rule 501 under the Securities Act of 1933, as amended).

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

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terms of the tender offer, which represents approximately 48% of the aggregate 13,780,449 warrants that were subject to the offer. The tender offer was made in reliance upon exemption from registration pursuant to Sections 3(a)(9), which provide an exemption for any security exchanged by the issuer with its existing security holders where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange. We did not pay or give any commission or other remuneration to any person for soliciting the tender offer. The tender offer also falls within Section 4(2) of the Securities Act since all the investors were current holders of the warrants and received their securities from the October 2004 private placement or from issuances in October 2004 pursuant to the terms of settlement agreements or convertible promissory notes. These transactions were conducted under Section 4(2) and the rules and regulations promulgated thereunder, including Regulation D.

In July 2005, we issued to our Chief Executive Officer, Michael Wilhelm, per his employment agreement, 150,000 stock options at a weighted average exercise price of \$0.44 per share under our 2003 Stock Option, Deferred Stock and Restricted Stock Plan.

In May 2005, per his employment agreement we issued 100,000 shares of our common stock to our Chief Financial Officer, John Fermanis. No general solicitation or advertising was undertaken in connection with the offer and sale of the shares. The Company's Chief Financial Officer qualifies as an "accredited investor" and acknowledged and agreed that the shares had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. The securities were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

The Company has accrued the issuance of 384,100 shares of common stock as of May 31, 2005. Pursuant to the terms of their respective agreement with us, 41,665 of these shares are to be issued to our Chief Financial Officer and 114,464 are to be issued to consultants per agreements for the first quarter 2005. Also included is 127,971 shares relating to the conversion of convertible notes. 100,000 of these shares are issued to two advisory board members. The shares will bear a restrictive legend regarding the sale or transfer of such. The shares 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. Our Chief Financial Officer and the consultants each qualifies as an accredited investor (as defined by Rule 501 under the Securities Act of 1933, as amended). No general solicitation or advertising was undertaken in connection with the offer and sale of these shares.

The Company accrued the issuance of 359,921 common stock purchase warrants during the three months ended March 31, 2005. The exercise prices of these warrants range from \$0.125 to \$0.50 per share. The warrants expire three years after date of issuance. Pursuant to the term of his employment agreement, our Chief Executive Officer, is to receive 79,388 warrants. Pursuant to the term of his employment agreement, our Chief Financial Officer, is to receive 12,500 warrants. Pursuant to the terms of their respective agreement with us, 268,033 of these warrants are to be granted to current members of the Bioterrorism Advisory Board, Drug Development Advisory Board and the Oncology and Dermatology Advisory Board for participation during the first quarter ended March 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 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

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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.

On June 13, 2005, the Company issued 80,000 shares of common stock for cash of \$4,000 pursuant to the exercise of a warrant at \$0.05 per share. On April 15, 2004, the Company entered into a \$5,000 Convertible Promissory Note bearing 12% interest for a term of 60 days to an individual investor. The term of the Note was extended to June 30, 2004. As additional incentive to the extension of the note, the investor was issued 5-year warrants to purchase up to 40,000 shares of common stock at \$0.05 per share. The term of the Note was again extended to October 16, 2004, the closing date of the Private Placement. As additional incentive to the extension of the note, the investor was issued 5-year warrants to purchase up to 40,000 shares of common stock at \$0.05 per

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share. Immediately upon the closing of the Private Placement, and in accordance with the terms of the Promissory Note, the principal of \$5,000 and \$299.56 of accrued interest was repaid to the investor releasing the Company from any further obligation under the warrants. The investor was financially able to bear the economic risk of the investment and capable of evaluating the merits and risks of the acquisition of the warrants. The investor also had received and reviewed all information necessary or appropriate for deciding whether to purchase the shares, including the Company's periodic SEC reports. No general solicitation or advertising was undertaken in connection with the offer and sale of the warrants. The investor represented to the Company that the investor was purchasing the warrants for the investor's own account and not with a present view towards the distribution thereof. In addition, the investor acknowledged and agreed that the warrants and the underlying securities had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

On September 28, 2001, the Company entered into a \$50,000 Convertible Promissory Note bearing 8% interest per month with an accredited investor. On June 7, 2005 in accordance with the terms of the Promissory Note, the outstanding principal and accrued interest was converted into 232,153 shares of our common stock releasing the Company from any further obligation under the Note. No general solicitation or advertising was undertaken in connection with the offer and sale of the Note and the shares. The investor represented to the Company that the investor was purchasing the securities for the investor's own account and not with a present view towards the distribution thereof. In addition, each investor acknowledged and agreed that the note and the shares had not been registered under the Securities Act and may not be offered or sold unless subsequently registered and/or offered, sold or transferred pursuant to an exemption from the registration requirements. Therefore, the Company believes that the securities were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

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. 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 September 30, 2005. The warrants will bear a restrictive legend regarding the sale or transfer of such

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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 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 nine months ended September 30, 2005, the Company accrued the issuance of 3,827,960 shares of common stock and warrants to purchase an additional 1,507,280 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.

### ITEM 27 EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

#### (A) EXHIBITS

EXHIBIT NUMBER	DESCRIPTION OF EXHIBIT
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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

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EXHIBIT NUMBER	DESCRIPTION OF EXHIBIT
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	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

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- 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
- 3.1(e) Certificate of Amendment filed with the Delaware Secretary of State on November 7, 1995 (incorporated by reference to exhibit 3.1(e) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
- 3.1(f) Certificate of Amendment filed with the Delaware Secretary of State on December 30, 1996 (incorporated by reference to exhibit 3.1(f) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
- 3.1(g) Certificate of Amendment filed with the Delaware Secretary of State on November 8, 2000 (incorporated by reference to exhibit 3.1(h) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
- 3.2 Amended and Restated Bylaws of the Registrant dated as of January 1, 2002 (incorporated by reference to exhibit 3(b) of the Registrant's annual report on Form 10-KSB for the year ended December 31, 2001 filed with the Securities and Exchange Commission on April 16, 2002).
- 4.1\* Specimen Common Stock Certificate.
- 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.
- 5.1\* Opinion of Kirkpatrick & Lockhart Nicholson Graham LLP

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EXHIBIT NUMBER	DESCRIPTION OF EXHIBIT
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10.1+	Employment Agreement dated December 16, 2002 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, and Michael Wilhelm.
10.2+	Consulting Agreement dated December 16, 2002 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, and David Harris.
10.2(a)+	First Amendment to Consulting Agreement dated January 2003 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, and David Harris.
10.3+	Consulting Agreement dated December 16, 2002 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, and Mark Witten.
10.3(a)+	First Amendment to Consulting Agreement dated January 2003 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, and Mark Witten.
10.4+	License Agreement dated December 16, 2002 among ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, David Harris and Mark Witten.
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.
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.
10.4(c)+	Assignment Agreement dated February 23, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Mark Witten.
10.4(d)+	Assignment Agreement dated February 23, 2005 among ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, David Harris and Mark Witten.
10.4(e)+	Assignment Agreement dated November 7, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Mark Witten.
10.4(f)+	Assignment Agreement dated November 7, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Mark Witten.
10.4(g)+	Assignment Agreement dated November 7, 2005 between



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ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Mark Witten.

10.4(h)+ Assignment Agreement dated November 7, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Mark Witten.

10.5+ Lease Agreement dated July 1, 2004 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant, and The Clayton Companies.

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).

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

10.8 Form of Subscription Agreement entered into as of October 26, 2004 between the Registrant and each of the Investors set forth on the Schedule of Investors thereto (incorporated by reference to exhibit 10.1 of the Registrant's current report on Form 8-K filed with the Securities and Exchange Commission on October 27, 2004).

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).

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- 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.
- 10.15+ Proforma invoice/quotation dated November 7, 2005 from Sigma-Aldrich, Inc. to ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant.
- 10.16+ Letter of acceptance dated October 2, 2003, from Huntingdon Life Sciences to ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant.
- 10.17 Price Quotation dated June 27, 2003 received by ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant from AppTec Laboratory Services.
- 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).
- 10.19 Consulting Agreement dated November 3, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Dr. Jack Caravelli, Ph.D.
- 10.20 Consulting Agreement dated July 29, 2005 between ImmuneRegen BioSciences, Inc., a subsidiary of the Registrant and Dr. Kelly McQueen, MD, MPH.
- 21.1+ Subsidiaries of Registrant.
- 23.1 Consent of Russell Bedford Stefanou Mirchandani LLP.
- 23.2\* Consent of Kirkpatrick & Lockhart Nicholson Graham, LLP contained in Exhibit 5.1).
- 24.1+ Power of Attorney (included on signature page).

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+ Previously filed.

\* To be filed by amendment.

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### (B) FINANCIAL STATEMENT SCHEDULES

All such schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

### ITEM 28 UNDERTAKINGS

The undersigned small business issuer hereby undertakes to:

(1) For determining any liability under the Securities Act, treat the information omitted from this form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the small business issuer under Rule 424(b)(1), or (4) or 497(h) under the Securities Act of 1933 as part of this registration statement as of the time the Securities and Exchange Commission declared it effective.

(2) For determining any liability under the Securities Act of 1933, treat each post-effective amendment that contains a form of prospectus as a new registration statement for the securities offered in this registration statement, and that offering of the securities at that time as the initial BONA FIDE offering of those securities.

The undersigned small business issuer hereby undertakes with respect to the securities being offered and sold in this offering:

(1) To file, during any period in which it offers or sells securities, a post-effective amendment to this Registration Statement to:

(a) Include any prospectus required by Section 10(a)(3) of the Securities Act;

(b) Reflect in the prospectus any facts or events which, individually or together, represent a fundamental change in the information in this registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from

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the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(c) Include any additional or changed material information on the plan of distribution.

(2) For determining liability under the Securities Act of 1933, treat each post-effective amendment as a new registration statement of the securities offered, and the offering of the securities at that time to be the initial BONA FIDE offering.

(3) File a post-effective amendment to remove from registration any of the securities that remain unsold at the end of the offering.

(4) For determining liability of the undersigned small business issuer

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under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned small business issuer undertakes that in a primary offering of securities of the undersigned small business issuer pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned small business issuer will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(a) Any preliminary prospectus or prospectus of the undersigned small business issuer relating to the offering required to be filed pursuant to Rule 424;

(b) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned small business issuer or used or referred to by the undersigned small business issuer;

(c) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned small business issuer or its securities provided by or on behalf of the undersigned small business issuer; and

(d) Any other communication that is an offer in the offering made by the undersigned small business issuer to the purchaser.

Insofar as indemnification by the undersigned small business issuer for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the small business issuer pursuant to the foregoing provisions, or otherwise, the small business issuer has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933, and is, therefore, unenforceable.

In the event that a claim for indemnification against such liabilities (other than the payment by the small business issuer of expenses incurred or paid by a director, officer or controlling person of the small business issuer in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the undersigned small business issuer will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

### SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Scottsdale, State of Arizona, on the 22nd day of February, 2006.

IR BioSciences Holdings, Inc.

By: /s/ Michael K. Wilhelm

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Michael K. Wilhelm  
President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the

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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)	February 22, 2006
/s/ John N. Fermanis ----- John N. Fermanis	Chief Financial Officer (Principal Financial and Accounting Officer)	February 22, 2006
----- Mark L. Witten, Ph.D.	Director	February 22, 2006
* ----- Theodore E. Staahl, M.D.	Director	February 22, 2006
*By: /s/ Michael K. Wilhelm ----- Michael K. Wilhelm Attorney in Fact		