IR BIOSCIENCES HOLDINGS INC
Form SB-2
June 14, 2007

As filed with the Securities and Exchange Commission on June 14, 2007

Registration no. 333-120784

United States
Securities and Exchange Commission
Washington, D.C. 20549

Form SB-2

Registration Statement under the Securities Act of 1933

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
(480) 922-3926
(Name, address and telephone number of agent for service)

Copies to
Thomas J. Poletti, Esq.
Anh Q. Tran, Esq.
Eliel Flores, Esq.
Kirkpatrick & Lockhart Preston Gates Ellis LLP
10100 Santa Monica Blvd., 7th floor Los Angeles, CA 90067
Telephone **(310) 552-5000** Facsimile **(310) 552-5001**

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. x

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. o

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 registration statement number of the earlier effective registration statement for the same offering. o

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. o

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

CALCULATION OF REGISTRATION FEE

TITLE OF EACH CLASS OF SECURITIES TO BE REGISTERED	AMOUNT TO BE REGISTERED (1)	PROPOSED MAXIMUM OFFERING PRICE PER SHARE	PROPOSED MAXIMUM AGGREGATE OFFERING PRICE	AMOUNT OF REGISTRATION FEE
Common stock, $.001 par value (3)	40,347,423	$ 0.18 (2)	$ 7,262,536.14(2)	$ 781
Common stock, $.001 par value (4)	17,133,125	0.18 (2)	3,083,962.50(2)	332
Total Registration Fee				$ 1,113

(Footnotes to table on next page)

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(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 June 11, 2007.

(3) 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.

(4) 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.

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PROSPECTUS

Subject to Completion, Dated June 14, 2007

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.

57,480,548 SHARES

IR BIOSCIENCES HOLDINGS, INC.

COMMON STOCK

This prospectus relates to 57,480,548 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.

Our common stock is traded on the OTC Bulletin Board maintained by the National Association of Securities Dealers, Inc. under the symbol "IRBO." On June 11, 2007, the closing sales price for our common stock on the OTC Bulletin Board was $0.18 per share.

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

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.

The date of this prospectus is _____, 2007

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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

IR BioSciences Holdings, Inc. is a development stage biotechnology company. Through our wholly-owned subsidiary ImmuneRegen BioSciences, Inc., we are engaged in the research and development of potential drug candidates, Homspera™ and its derivatives, Radilex™ and Viprovex™. We defined Radilex and Viprovex as derivatives of Homspera due to the potential difference in formulations and indications for use of such compounds. Our goal is to develop these potential drug candidates to be used as possible countermeasures for homeland security threats, including radiological, chemical and biological agents, such as influenza and anthrax. We hope there may exist not only a market for products related to biodefense through governmental purchasing, but there also may exist a potential commercial market for treatments of cancer treatment side-effects and seasonal influenza.

Our patents, patent applications and continued research are derived from discoveries made during research studies related to the function of Substance P, which is found in the body and has a large number of actions. These studies were funded by the Air Force Office of Scientific Research (AFOSR) in the early 1990s and were conducted by research scientists, including our co-founders Drs. Mark Witten and David Harris. In the course of research on Substance P, these scientists created a number of synthetic analogues, structural derivatives with slight chemical differences, for study. One of these, which we have named Homspera, is the basis for our drug development efforts and our intellectual property. 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. There can be no assurance that our interpretation of the results of our studies will prove to be accurate after further testing and our beliefs regarding the potential uses of our drug candidates may never materialize.

Our current focus is on the development of two potential formulations derived from Homspera, Radilex and Viprovex.

We are researching Radilex for use as a potential treatment for acute exposure to radiation. To date we have sponsored seven studies and co-sponsored three studies all of which were conducted utilizing rodents. The results of these studies suggest Radilex may play a role in increased survival among tested rodents following exposure to lethal doses of gamma radiation. We believe that Radilex, if developed, may be an acceptable candidate to be marketed to governmental agencies for procurement. Further, we believe that a commercial market may exist for the use of Radilex as it relates to the treatment of radiation-induced side effects of cancer treatments, either as a stand alone treatment or as a co-therapeutic agent to be used with other therapies.

Viprovex is being researched by us for use in potential treatments of exposure to biological agents, such as infectious disease, which include influenza and anthrax. Based on early studies on Homspera and existing literature on Substance P, we are researching the efficacy of Viprovex as a potential treatment for exposure to chemical agents, such as formalin. To date we have sponsored three studies related to the treatment of influenza, three on the exposure to anthrax spores and one on exposure to formalin. We believe the results of these studies indicated potential efficacy in the use of Viprovex as both a stand alone treatment and an adjuvant, to be used in conjunction with other drugs. If Viprovex can be developed, we believe that potential applications may exist for sale to governments for the treatment of exposure to anthrax and pandemic influenza. In addition, we believe that potential commercial opportunities may

exist for the treatment of seasonal influenza and other viral or bacterial infections, either as a stand-along drug or as an adjuvant to other existing drugs.

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 the potential use of Radilex in the treatment of acute radiation syndrome and the other for the potential use of Viprovex in the treatment of avian influenza.

We have filed patent applications and provisional patent applications, for the use of Homspera and derivatives thereof. We own four registered patents, two issued U.S. and two issued foreign patents. We also have 39 pending patents, comprised of three pending Patent Cooperation Treaty (PCT) applications, ten pending U.S. provisional patent applications and 26 pending foreign provisional patent applications.

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Our potential drug candidates, Radilex and Viprovex, are at early, pre-clinical stages of development and may not be shown to be safe or effective and may never receive regulatory approval. Neither Radilex nor Viprovex have yet been tested in large animals or 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 such testing is permitted, none of Radilex, Viprovex or any other potential drug candidates, if any, derived from Homspera may be successfully developed or shown to be safe or effective.

The results of our pre-clinical studies may not be indicative of future clinical trial results. A commitment of substantial resources to conduct time-consuming research, pre-clinical studies and clinical trials will be required if we are to develop any commercial applications using Homspera or any derivatives thereof. Delays in planned patient enrollment in our future clinical trials may result in increased costs, program delays or both. None of our potential 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. In June 2006, our shareholders voted to increase the number of authorized shares of Common Stock to 250,000,000. 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.

THE OFFERING

Common stock offered by selling stockholders	57,480,548 shares(1)
Common stock outstanding	114,322,539 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

(1) Represents 40,347,423 shares of our common stock that were issued to selling stockholders and 17,133,125 shares of our common stock underlying warrants that were issued to selling stockholders.

(2) The number of shares of common stock outstanding as of June 11, 2007 listed above excludes:

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- 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;

- 6,014,212 shares of common stock issuable upon the exercise of options at a weighted average exercise price of $0.23 granted under our 2003 Stock Option, Deferred Stock and Restricted Stock Plan; 5,039,717 of which are currently exercisable;

- 35,295,647 shares of our common stock issuable upon exercise of warrants with exercise prices ranging from $0.01 to $2.00 per share; 31,399,814 of which are currently exercisable; and,

- 695,000 shares issuable upon exercise of warrants at an exercise price of $0.32 per share to be granted as per the terms of a service agreement if certain milestones are reached.

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.

Summary of Condensed Consolidated Statement of Losses
(Unaudited)

	For the Three Months Ended March 31,		For the Period October 30, 2002 to
	2007	**2006**	**March 31, 2007**
Revenues	$ -	$ -	$ -
Operating expenses:			
Selling, general and administrative expenses	$ 874,110	$ 561,144	$ 11,443,728
Merger fees and costs	-	-	350,000
Financing cost	-	-	90,000
Impairment of intangible asset costs	-	-	6,393
Total operating expenses	874,110	561,144	11,890,121
Operating loss	(874,110)	(561,144)	(11,890,121)
Other expense:			
Cost of penalty for late registration of shares	-	555,973	2,192,160
(Gain) loss from marking to market - warrant portion of penalty for late registration of shares	-	(6,868)	(378,198)
(Gain) loss from marking to market - stock portionof penalty for late registration of shares	-	52,423	(760,058)

Interest (income) expense, net	(20,866)	(166)	1,194,399
Total other (income) expense	(20,866)	601,362	2,248,303
Income (loss) before income taxes	(853,244)	(1,162,506)	(14,138,424)
Provision for income taxes	(8,115)	-	(8,115)
Net (loss)	$ (861,359)	$ (1,162,506)	$ (14,146,539)
Net income (loss) per share - basic and diluted	$ (0.01)	$ (0.02)	$ (0.28)
Weighted average shares outstanding - basic and diluted	113,914,576	69,475,429	50,879,773

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Summary of Condensed Consolidated Balance Sheet Data

	As of March 31, 2007 (Unaudited)	As of December 31, 2006
Assets		
Current assets		
Cash and cash equivalents	$ 2,124,695	$ 2,752,103
Prepaid services and other current assets	106,209	77,899
Salary advance	750	1,500
Total current assets	2,231,654	2,831,502
Deposits and other assets	2,260	2,260
Furniture and equipment, net of accumulated depreciation	31,396	28,242
Total assets	$ 2,265,310	$ 2,862,004
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 421,008	460,969
Current portion of notes payable	50,000	50,000
Total current liabilities	471,008	510,969
Commitments and Contingencies	-	-
Stockholders' Equity		
Preferred stock, $0.001 par value:		
10,000,000 shares authorized, no shares issued and outstanding	-	-
Common stock, $0.001 par value; 250,000,000 shares authorized;		
114,322,536 shares issued and outstanding at March 31, 2007 and 108,041,897 shares issued and outstanding at December 31, 2006	114,323	108,042
Additional paid-in capital	15,826,518	15,522,690
Common stock subscribed	-	5,483
Deficit accumulated during the development stage	(14,146,539)	(13,285,108)
Total stockholders’ equity	1,794,302	2,351,035
Total liabilities and stockholders' equity	$ 2,265,310	$ 2,862,004

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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. 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.

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, have generated no revenues to date are not currently profitable and expect to incur significant expenses in the near future.

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 three months ended March 31, 2007 was $861,539 As of March 31, 2007 we had an accumulated deficit of $14,146,539. Our net loss for the fiscal year ended December 31, 2006 and December 31, 2005 was $1,486,046 and $4,591,107 respectively. As of December 31, 2006, we had an accumulated deficit of $13,285,180.

As of March 31, 2007, we had a working capital of $1,760,646. This amount consists of cash of $2,124,695 and other current assets of $106,959 less accounts payable and accrued liabilities of $421,008 and notes payable of $50,000. As of December 31, 2006, we had working capital of $2,320,533. This amount consists of cash of $2,752,103 and prepaid services of $79,399 less accounts payable and accrued liabilities of $460,969, and notes payable of $50,000. We have incurred a net loss of $14,146,539 for the period from our inception in October 30, 2002 to March 31, 2007 and we have incurred a net loss of $13,285,180 for the period from our inception in October 2002 to December 31, 2006. We have always experienced negative cash flow. We expect to continue to experience negative cash flow and operating losses through at least 2010 and possibly thereafter. As a result, we will need to generate significant revenues to achieve profitability. We may never become profitable and as a result the value and market price of our common stock may substantially decline.

Our independent outside auditors have raised substantial doubt about our ability to continue as a going concern.

Our independent certified public accountants have stated in their report included on our annual report on SEC Form 10-KSB filed with the Securities and Exchange Commission on April 17, 2007 and Form 10-KSB/A filed with the Securities and Exchange Commission on April 30, 2007 that we have incurred a net loss and negative cash flows from operations of $1,486,046 and $2,035,484, respectively, for the year ended December 31, 2006. During the three months ended March 31, 2007, the Company used cash in operating activities of $621,404 and had a net loss of $861,359. From the date of inception (October 30, 2002) to March 31, 2007, the Company has had a net loss of $14,146,539 and has used cash of $6,615,346 in operating activities.

Our expectations to continue to incur net losses and negative cash flow from operations and a lack of operational history, among other matters, that raise substantial doubt about our ability to continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. The effect of this going concern would materially and adversely affect our ability to raise capital, our relationship with potential suppliers and customers, and have other unforeseen effects.

We will be required to raise additional capital to fund our operations. If we cannot raise needed additional capital in the future, we will be required to cease operations.

Based on our current plans, we believe our existing financial resources, and interest earned thereon, will be sufficient to meet our operating expenses and capital requirements through January 2008. 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 an additional $2.5 million over the next 24 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.

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You should be aware that in the future:

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

If we cannot raise additional funds when needed, or on acceptable terms, we will not be able to continue to develop our drug candidates. We require substantial working capital to fund our operations. Since we do not expect to generate any revenues in the foreseeable future, in order to fund operations, we will be completely dependent on additional debt and equity financing arrangements. There is no assurance that any financing will be sufficient to fund our capital expenditures, working capital and other cash requirements beyond January 2008. No assurance can be given that any such additional funding will be available or that, if available, can be obtained on terms favorable to us. If we are unable to raise needed funds on acceptable terms, we will not be able to develop or enhance our products, take advantage of any future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, we will not be able to continue operations.

We have deferred, and may continue to defer, payment of some of our obligations, which may adversely affect our ability to obtain goods and services in the future.

We estimate that we will require approximately $2.5 million to meet our expenses for the next 24 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. There is no guarantee that we will be able to defer payment of any of our obligations, at which point we will be forced to find immediate funding to settle such obligations. If we do not find such funding, we may not be able obtain the services and goods needed to continue our operations.

We will need to conduct significant additional research, preclinical testing and clinical testing and expect to incur losses as we research, develop and seek regulatory approvals for our potential products.

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

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

Our operating expenses are unpredictable, which may adversely affect our business, operations and financial condition.

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

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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.

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

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

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

If we do not obtain government regulatory approval for our products, we cannot sell our products and we will not generate revenues.

Our principal development efforts are currently centered on Radilex and Viprovex, which are potential drug candidates derived from 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 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 Homspera. In addition, we plan to utilize Homspera 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 Homspera, we may have to modify or cease production of the products. As all of our applications utilize or will utilize Homspera, any findings that Homspera is unsafe or ineffective would severely harm our business operations, since all of our primary revenue sources would be negatively affected by such findings.

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If we fail to successfully develop and commercialize products, we will have to cease operations.

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

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

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

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

If Radilex, our current potential drug candidate to treat aspects of acute radiation syndrome (ARS) and Viprovex, our potential drug candidate to treat exposure to various biological and chemical 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, if any, of procurement orders by the U.S. and foreign governments. While a number of governments have historically stockpiled drugs to treat indications such as smallpox, anthrax exposure, plague, tularemia and certain long-term effects of radiation exposure, we are unaware of any significant stockpiling orders for drugs to treat ARS.

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

Any decision by the U.S. Government to enter into a commitment to purchase Radilex or Viprovex prior to FDA approval is largely out of our control. Our development plans and timelines may vary substantially depending on whether we receive such a commitment and the size of such commitment, if any. In addition, even if Radilex or Viprovex is approved by regulatory authorities, we cannot guarantee that we will receive any purchase 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 small animals. We may not be able to obtain the necessary approvals for clinical trials, manufacturing or marketing of Radilex and Viprovex or any other potential products, if any, derived from Homspera. Moreover, any significant delays in clinical trials will impede our ability to commercialize our applications and generate revenue and could significantly increase our development costs. The commencement and completion of clinical trials for Radilex, Viprovex or any other potential products, if any, derived from Homspera, could be delayed or prevented by a variety of factors, including:

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

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

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

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 potential future products and our business could suffer.

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

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

If we fail to obtain approval from foreign regulatory authorities, we will not be allowed to market or sell our potential products in other countries, which would adversely affect our levels of future revenues, if any.

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

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

Clinical trials may fail to demonstrate the safety and efficacy of our potential drug candidates, the effect of which could prevent or significantly delay regulatory approval and therefore adversely affect the timing and level of future revenues, if any.

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

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

may severely harm our business and reputation.

Delays in the conduct or completion of our pre-clinical or clinical studies or the analysis of the data from our pre-clinical or clinical studies may result in delays in our planned filings for regulatory approvals or adversely affect our ability to enter into collaborative arrangements.

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

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

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

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

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 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 Homspera 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.

For the manufacture of Radilex, Viprovex and Homspera, we obtain synthetic peptides from third party manufacturers. If any of these proposed manufacturing operations prove inadequate, there may be no assurance that any other arrangements may be established on a timely basis or that we could establish other manufacturing capacity on a timely basis. Our dependence on such manufacturers may delay or impair our ability to generate revenues, or adversely affect our profitability.

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We rely on arrangements with contract manufacturing companies in order to meet requirements for Radilex, Viprovex and Homspera. By choosing 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 potential profit margins, if any, and our ability to develop and deliver proposed products on a timely and competitive basis.

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.

Even if we are permitted to market our potential products, adverse determinations concerning product pricing, reimbursement and related matters could prevent us from successfully commercializing Radilex, Viprovex and Homspera which would adversely affect our level of future revenues, if any.

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

The medical community may not accept and utilize Radilex, Viprovex or any other potential product, if any, derived from Homspera, the effect of which would prevent us from successfully commercializing any proposed product and adversely affect our level of future revenue, if any.

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

Product liability exposure may expose us to significant liability or costs which would adversely impart our future operating results and divert funds from the operation of our business.

We face an inherent business risk of exposure to product liability and other claims and lawsuits in the event that the development or use of our technology or prospective products is alleged to have resulted in adverse 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. We also have 39 pending patents relating to the use of Sar^9, Met $(O_2)^{11}$-Substance P, comprised of three pending Patent Cooperation Treaty (PCT) applications, ten pending U.S. provisional patent applications and 26 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.

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

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

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

Our rights to the US Patent Nos. 5,945,508 and 5,998,376, Substance P Treatment for Immunostimulation, are limited by the rights of the University of Arizona and the United States Air Force and as a result, our ability to use of the patent in our business is also limited. Due to these limitations, we may not be able to use the patent in the most profitable or efficient manner and, as a result, our results of operations may suffer. 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.

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Further, because our patents are based on research funded by the government, the U.S. Government has certain rights in any technology developed. These rights include a non-exclusive, paid-up, worldwide license under such inventions for any governmental purpose. In addition, 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.

As a result, our potential future revenues, if any, may be lessened. Additionally, our profit margins, if any, may be lessened as our cost of goods may increase if we are mandated to manufacture our products substantially in the United States. Additionally, the U.S. Government may elect to manufacture and use any products based on our technology without paying us any revenue.

Our patents and proprietary technology may not be enforceable and the patents and proprietary technology of others may prevent us from commercializing products, which would adversely affect our level of future revenues, if any.

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

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

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

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

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

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

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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, and Hal Siegel, Ph.D., our Senior Director, Product Development and Regulatory Affairs. We currently maintain a key-man insurance policy on Mr. Wilhelm and Dr. Siegel for $1,000,000 and $250,000 respectively, payable to the company, on their lives. While we have entered into employment agreements with Mr. Wilhelm and Dr. Siegel, the loss of any of their services would be detrimental to us and could have a material adverse effect on our business, financial condition and results of operations.

Risks Related To This Offering

A limited prior public market and trading market may cause volatility in the price of our common stock.

Our common stock is currently traded on a limited basis on the OTC Bulletin Board (the "OTCBB") under the symbol "IRBO". The OTCBB is an inter-dealer, Over-The-Counter market that provides significantly less liquidity than the NASDAQ Stock Market. 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 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.

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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. 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 periods may, under certain circumstances, sell within any three-month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of our common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitations, by a non-affiliate of our company who has satisfied a two-year holding period. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have an adverse effect on the market price of our securities.

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

Our common stock is considered a "penny stock," and is subject to additional sale and trading regulations that may make it more 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 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.

NOTE REGARDING THIS PROSPECTUS

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.

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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:

- Our ability to raise additional funding and the amounts raised, if any;
- Our ability to successfully develop and commercialize any other proposed products, if any, derived from Homspera;
- 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;
- 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;
- The degree and nature of our competition;
- Our ability to employ and retain qualified employees; and,
- 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."

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.

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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 REGISTRANT'S COMMON STOCK AND RELATED STOCKHOLDER MATTERS

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

	2007	
	High	**Low**
1st Quarter	$ 0.17	$ 0.12
2nd Quarter (through June 11, 2007)	0.22	0.12

	2006	
	High	**Low**
1st Quarter	$ 0.35	$ 0.20
2nd Quarter	0.51	0.27
3rd Quarter	0.30	0.14
4th Quarter	0.29	0.13

	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

On June 11, 2007, the closing price of our common stock as reported by the OTC Bulletin Board was $0.18 per share. There were approximately 1,200 shareholders of record and beneficial stockholders of our common stock as of June 11, 2007. We have not paid any dividends on our common stock since inception and do not intend to do so in the foreseeable future.

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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 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 elsewhere 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

IR BioSciences Holdings, Inc. is a development stage biotechnology company. Through our wholly-owned subsidiary ImmuneRegen BioSciences, Inc., we are engaged in the research and development of potential drug candidates, Homspera™ and its derivatives, Radilex™ and Viprovex™. We defined Radilex and Viprovex as derivatives of Homspera due to the potential difference in formulations and indications for use of such compounds. Our goal is to develop these potential drug candidates to be used as possible countermeasures for homeland security threats, including radiological, chemical and biological agents, such as influenza and anthrax. We hope there may exist not only a market for products related to biodefense through governmental purchasing, but there also may exist a potential commercial market for treatments of cancer treatment side-effects and seasonal influenza.

Our patents, patent applications and continued research are derived from discoveries made during research studies related to the function of Substance P, which is found in the body and has a large number of actions. These studies were funded by the Air Force Office of Scientific Research (AFOSR) in the early 1990s and were conducted by

research scientists, including our co-founders Drs. Mark Witten and David Harris. In the course of research on Substance P, these scientists created a number of synthetic analogues, structural derivatives with slight chemical differences, for study. One of these, which we have named Homspera, is the basis for our drug development efforts and our intellectual property. 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. There can be no assurance that our interpretation of the results of our studies will prove to be accurate after further testing and our beliefs regarding the potential uses of our drug candidates may never materialize.

Our current focus is on the development of two potential formulations derived from Homspera, Radilex and Viprovex.

We are researching Radilex for use as a potential treatment for acute exposure to radiation. To date we have sponsored seven studies and co-sponsored three studies all of which were conducted utilizing rodents. The results of these studies suggest Radilex may play a role in increased survival among tested rodents following exposure to lethal doses of gamma radiation. We believe that Radilex, if developed, may be an acceptable candidate to be marketed to governmental agencies for procurement. Further, we believe that a commercial market may exist for the use of Radilex as it relates to the treatment of radiation-induced side effects of cancer treatments, either as a stand alone treatment or as a co-therapeutic agent to be used with other therapies.

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Viprovex is being researched by us for use in potential treatments of exposure to biological agents, such as infectious disease, which include influenza and anthrax. Based on early studies on Homspera and existing literature on Substance P, we are researching the efficacy of Viprovex as a potential treatment for exposure to chemical agents, such as formalin. To date we have sponsored three studies related to the treatment of influenza, three on the exposure to anthrax spores and one on exposure to formalin. We believe the results of these studies indicated potential efficacy in the use of Viprovex as both a stand alone treatment and an adjuvant, to be used in conjunction with other drugs. If Viprovex can be developed, we believe that potential applications may exist for sale to governments for the treatment of exposure to anthrax and pandemic influenza. In addition, we believe that potential commercial opportunities may exist for the treatment of seasonal influenza and other viral or bacterial infections, either as a stand-along drug or as an adjuvant to other existing drugs.

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 the potential use of Radilex in the treatment of acute radiation syndrome and the other for the potential use of Viprovex in the treatment of avian influenza.

We have filed patent applications and provisional patent applications, for the use of Homspera and derivatives thereof. We own four registered patents, two issued U.S. and two issued foreign patents. We also have 39 pending patents, comprised of three pending Patent Cooperation Treaty (PCT) applications, ten pending U.S. provisional patent applications and 26 pending foreign provisional patent applications.

Our potential drug candidates, Radilex and Viprovex, are at early, pre-clinical stages of development and may not be shown to be safe or effective and may never receive regulatory approval. Neither Radilex nor Viprovex have yet been tested in large animals or 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 such testing is permitted, none of Radilex, Viprovex or any other potential drug candidates, if any, derived from Homspera may be successfully developed or shown to be safe or effective.

The results of our pre-clinical studies and clinical trials may not be indicative of future clinical trial results. A commitment of substantial resources to conduct time-consuming research, pre-clinical studies and clinical trials will be required if we are to develop any commercial applications using Homspera or any derivatives thereof. Delays in planned patient enrollment in our future clinical trials may result in increased costs, program delays or both. None of our potential 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.

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.

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Product Research and Development

We incurred an expense of $76,834 for the three months ended March 31, 2007 in research and development activities related to the development of Radilex and Viprovex versus an expense of $111,516 for the three months ended March 31, 2006. 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 $1,103,431 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 compensation for Dr. Siegel have been classified in officer's salaries for consistency of financial reporting.

We anticipate that during the next 12 months we will increase our research and development spending to a total of approximately $700,000 in an effort to further develop Radilex and Viprovex. This research and development cost estimate includes additional animal pharmacology studies, formulation and animal safety/toxicity studies. If we receive additional funds, through either investment funding or grants, we expect we will increase our research and development spending.

We believe we will be able to apply to the FDA for approval for the use of Radilex for the treatment of acute radiation syndrome and for approval for the use of Viprovex for the treatment of maladies caused by exposure to biological and chemical agents based upon the "animal efficacy rule." Therefore, we intend to apply for approval based upon a 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 rule, in situations where it would be unethical to conduct traditional 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. Under either the animal efficacy rule or traditional efficacy rules, 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.

If we are successful in completing our studies and the results are as we anticipate, we intend to prepare and submit the necessary documentation to the FDA and other regulatory agencies for approval. If approval for Radilex and/or Viprovex is granted, we expect to begin efforts to commercialize our product, if any, immediately thereafter, however, since we are currently in the pre-clinical stage of development, it will take an indeterminate amount of time in development before we have a marketable drug, if ever.

We believe that initial revenues, if any, will likely be generated through partnerships, alliances and/or licensing agreements with pharmaceutical or biotechnology companies. Our focus during the next 24 months will be to identify those companies which we believe may have an interest in our proposed products and attempt to negotiate arrangements for potential partnerships, alliances and/or licensing arrangements. Alliances between pharmaceutical and biotechnology companies can take a variety of organizational forms and involve many different payment structures such as upfront payments, milestone payments, equity injections and royalty payments. To date, we have not entered into discussions with and have no agreements or arrangements with any such companies. Even if we are successful in entering into such a partnership or alliance or licensing our technology, we anticipate that the earliest we may begin to generate revenues from operations would be calendar 2009. There is no assurance that we will ever be successful in reaching such agreements or ever generate revenues from operations.

We will need to generate significant revenues from product sales and or related royalties and license agreements to achieve and maintain profitability. Through March 31, 2007, we had no revenues from any product sales, royalties or

licensing fees, and have not achieved profitability on a quarterly or annual basis. Our ability to achieve profitability depends upon, among other things, our ability to develop products, obtain regulatory approval for products under development and enter into agreements for product development, manufacturing and commercialization. Moreover, we may never achieve significant revenues or profitable operations from the sale of any of our potential products or technologies.

Number of Employees

From our inception through June 11, 2007, we have relied and continue to rely on the services of outside consultants for services and currently have seven total employees, five full-time employees and two part-time employees. Our full-time employees are Michael K. Wilhelm, our Chief Executive Officer; John N. Fermanis, our Chief Financial Officer; Hal N. Siegel, Ph.D., Senior Director, Product Development and Regulatory Affairs, Chris Romano, Scientific Associate; and, the fifth 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 12 months.

CRITICAL ACCOUNTING POLICIES

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

Effective January 1, 2006, the Company adopted SFAS No. 123 (revised), "Share-Based Payment" (SFAS 123(R)) utilizing the modified prospective approach. Prior to the adoption of SFAS 123(R) we accounted for stock option grant in accordance with APB Opinion No. 25, "Accounting for Stock Issued to Employees" (the intrinsic value method), and accordingly, recognized compensation expense for stock option grants.

Under the modified prospective approach, SFAS 123(R) applies to new awards and to awards that were outstanding on January 1, 2006 that are subsequently modified, repurchased or cancelled. Under the modified prospective approach, compensation cost recognized in the nine months of fiscal 2006 includes compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS 123, and compensation cost for all share-based payments granted subsequent to January 1, 2006 based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R). Prior periods were not restated to reflect the impact of adopting the new standard.

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Recent Accounting Pronouncements

In February 2006, the FASB issued SFAS No. 155. "*Accounting for certain Hybrid Financial Instruments an amendment of FASB Statements No. 133 and 140,"* or SFAS No. 155. SFAS No. 155 permits fair value remeasurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation, clarifies which interest-only strips and principal-only strips are not subject to the requirements of Statement No. 133, establishes a requirement to evaluate interests in securitized financial assets to identify interests that are freestanding derivatives or that are hybrid financial instruments that contain an embedded derivative requiring bifurcation, clarifies that concentrations of credit risk in the form of subordination are not embedded derivatives, and amends SFAS No. 140 to eliminate the prohibition on a qualifying special purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument. SFAS 155 is effective for all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006. We do not expect the adoption of SFAS 155 to have a material impact on our consolidated financial position, results of operations or cash flows.

In March 2006, the FASB issued FASB Statement No. 156, Accounting for Servicing of Financial Assets - an amendment to FASB Statement No. 140. Statement 156 requires that an entity recognize a servicing asset or servicing liability each time it undertakes an obligation to service a financial asset by entering into a service contract under certain situations. The new standard is effective for fiscal years beginning after September 15, 2006. The adoption of SFAS No.156 did not have a material impact on the Company's financial position and results of operations.

In July 2006, the FASB issued Interpretation No. 48 (FIN 48). "*Accounting for uncertainty in Income Taxes"*. FIN 48 clarifies the accounting for Income Taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition and clearly scopes income taxes out of SFAS 5, "*Accounting for Contingencies"*. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company does not expect adoption of this standard will have a material impact on its financial position, operations or cash flows.

In September 2006 the Financial Account Standards Board (the "FASB") issued its Statement of Financial Accounting Standards 157, Fair Value Measurements. This Statement defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles (GAAP), and expands disclosures about fair value measurements. This Statement applies under other accounting pronouncements that require or permit fair value measurements, the Board having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, this Statement does not require any new fair value measurements. However, for some entities, the application of this Statement will change current practice. FAS 157 effective date is for fiscal years beginning after November 15, 2007. The Company does not expect adoption of this standard will have a material impact on its financial position, operations or cash flows.

In September 2006 the FASB issued its Statement of Financial Accounting Standards 158 "Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans". This Statement improves financial reporting by requiring an employer to recognize the overfunded or underfunded status of a defined benefit postretirement plan (other than a multiemployer plan) as an asset or liability in its statement of financial position and to recognize changes in that funded status in the year in which the changes occur through comprehensive income of a business entity or changes in unrestricted net assets of a not-for-profit organization. This Statement also improves financial reporting by requiring an employer to measure the funded status of a plan as of the date of its year-end statement of financial position, with limited exceptions. The effective date for an employer with publicly traded equity securities is as of the end of the fiscal year ending after December 15, 2006. The Company does not expect adoption of this standard will have a material impact on its financial position, operations or cash flows

In February 2007, the FASB issued SFAS No. 159, “The Fair Value Option for Financial Assets and Financial Liabilities.” SFAS 159 permits entities to choose to measure many financial instruments, and certain other items, at fair value. SFAS 159 applies to reporting periods beginning after November 15, 2007. The adoption of SFAS 159 is not expected to have a material impact on the Company’s financial condition or results of operations.

Results of Operations for the Three Month Periods Ended March 31, 2007 and March 31, 2006

Revenue

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.

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Costs and Expenses

From our inception through March 31, 2007, we have incurred losses of $14,146,539. These expenses were associated principally with equity-based compensation to employees and consultants, product development costs and professional services, and equity based compensation to shareholders for the penalty incurred for the late registration of shares.

Sales, General, and Administrative Expenses

Sales, general, and administrative expenses ("SG&A") were $874,110 for the three months ended March 31, 2007, an increase of $312,966 or approximately 56% compared to SG&A of $561,144 during the three months ended March 31, 2006. The increase is primarily due to higher costs for officer compensation, non-cash compensation and public relations. For the three months ended March 31, 2007, this amount consisted primarily of officer compensation of $235,864, inclusive of an incentive bonus of $82,239 in cash for Michael K. Wilhelm, President and C.E.O. per the terms of his employment agreement, public relations and marketing of $115,262, legal and accounting fees of $114,271, non-cash compensation costs of $182,920, research and development of $76,834, other consulting fees of $25,854 and payroll and related costs of $19,826.

We expect SG&A to increase during the coming twelve months as we continue to build out our infrastructure and to develop our potential drugs and therapeutics.

Late Registration Penalty

The cost of penalties for the late registration of shares, including cost adjustments for marking to market, was $0 for the three months ended March 31, 2007, a decrease of $601,528 compared to late registration penalty costs of $601,528 charged to other expense during the three months ended March 31, 2006.

Interest Income (net)

Interest income (net) was $20,866 for the three months ended March 31, 2007, an increase of $20,700 or approximately 12,469% compared to interest income of $166 for the three months ended March 31, 2006. Interest income increased during the three months ended March 31, 2007 due to higher cash balances from the Private Placement in the fourth quarter of 2006.

We expect interest income to decrease during the coming twelve months as we use the proceeds from the Private Placement to fund operations.

Net Loss

For the reasons stated above our net loss for the three months ended March 31, 2007 was $861,359 or $0.01 per share, a decrease of $301,147 or approximately 26% compared to a net loss of $1,162,506 for the three months ended March 31, 2006.

For the reasons stated above, our net loss for the twelve months ending December 31, 2006 was $1,486,046, or $0.02 per share and our net loss for the three months ended March 31, 2007 was $861,359 or $0.01 per share. From the date of inception (October 30, 2002) to March 31, 2007, we had a net loss of $14,146,539 or $0.28 per share. We expect that losses will continue at least through the period ending December 31, 2009.

We have incurred a net loss and negative cash flows from operations of $1,486,046 and $2,035,484 respectively, for the year ended December 31, 2006. This loss, in addition to a lack of operational history, raises substantial doubt about our ability to continue as a going concern. In the absence of significant revenue and profits, and since we do not expect to generate significant revenues in the foreseeable future, we, in order to fund operations, will be completely dependent on additional debt and equity financing arrangements. There is no assurance that any financing will be sufficient to fund our capital expenditures, working capital and other cash requirements for the fiscal year ending December 31, 2007. No assurance can be given that any such additional funding will be available or that, if available, can be obtained on terms favorable to us. If we are unable to raise needed funds on acceptable terms, we will not be able to develop or enhance our products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, we will not be able to continue operations.

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 continue our research and development efforts on our early, pre-clinical stage products and build out our corporate infrastructure.

Results of Operations for the Twelve Month Periods Ended December 31, 2006 And 2005

Revenues

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

Costs and Expenses

From our inception through December 31, 2006, we have incurred losses of $13,285,180. These expenses were associated principally with equity-based compensation to employees and consultants, product development costs and professional services, and equity based compensation to shareholders for the penalty incurred for the late registration of shares.

For the twelve months ending December 31, 2006, Sales, General and Administrative expenses (“SG&A”) were $2,445,317, a decrease of $89,100 or approximately 4% compared to SG&A expenses of $2,534,417 during the 12 months ended December 31, 2005. The decrease was primarily due to lower costs for non-cash compensation.

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For the twelve months ending December 31, 2006, Interest Expense (net) was $48,508, an increase of approximately 526% compared to Interest Income (net) of $11,386 during the 12 months ended December 31, 2005. Interest Expense increased because the Company entered into notes payable during the twelve months ended December 31, 2006. We expect Interest Expense to decrease during the coming twelve months as we have paid off outstanding notes payable with the proceeds of the Private Placement.

During the twelve months ending December 31, 2006, we recognized a gain of $438,601 for the cost of the penalty for the late registration of shares which was a decrease of $3,069,362 or approximately 117% compared to the cost of penalty for late registration of shares for the twelve months ended December 31, 2005. The reduction of the expense was due to stopping the accrual of penalty shares in 2006 and the reversal of the accrual for penalty shares and warrants which had been previously accrued in excess of the cap amount agreed to by the shareholders.

Net Loss

For the reasons stated above, our net loss for the twelve months ending December 31, 2006 was $1,486,046, or $0.02 per share versus a net loss for the twelve months ending December 31, 2005 of $4,591,107 or $0.07 per share. For the period of inception (October 30, 2002) through December 31, 2006, our net loss was $13,285,180, or $0.28 per share. We expect that losses will continue through the period ending December 31, 2010.

Our independent certified public accountants have stated in their report included in this Form 10-KSB that we have incurred a net loss and negative cash flows from operations of $1,486,046 and $2,035,484, respectively, for the year ended December 31, 2006. This loss, in addition to a lack of operational history, raises substantial doubt about our ability to continue as a going concern. We currently have sufficient working capital to fund operations through January 2008. In the absence of significant revenue and profits, and since we do not expect to generate significant revenues in the foreseeable future, we, in order to fund future operations, will be completely dependent on additional debt and equity financing arrangements. There is no assurance that any financing will be sufficient to fund our capital expenditures, working capital and other cash requirements beyond January 2008. No assurance can be given that any such additional funding will be available or that, if available, can be obtained on terms favorable to us. If we are unable to raise needed funds on acceptable terms, we will not be able to develop or enhance our products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, we will not be able to continue operations.

Penalties for Late Registration

During the three months ended March 31, 2006, we accrued the issuance of 1,383,600 shares of common stock and warrants to purchase an additional 544,800 shares of common stock pursuant to a penalty calculation with regard to the late registration of shares sold in a private placement in October 2004.

In October 2004, we completed a private placement sale of shares of our common stock and warrants to purchase additional shares of common stock. We issued in the private placement an aggregate of 19,600,000 shares of our common stock and warrants to purchase 9,800,000 shares of our common stock. We agreed to register these shares along with the shares underlying these warrants within ninety days from the closing date of the transaction, or we would incur a penalty equivalent to an additional 2% of the shares and warrants to be registered for every 30 days that we fail to complete this registration. This penalty amounted 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 March 31, 2006, we were required to issue an additional 6,625,907 shares of common stock and warrants to purchase an additional 2,724,000 shares of common stock. At the time these liabilities were incurred, the shares were valued at $2,448,511 and the warrants were valued at $744,177. The shares were valued at the market price of the Company's common stock at the

time the liabilities were incurred. The warrants were valued utilizing the Black-Scholes valuation model. The aggregate amount of $555,973 was charged to operations as cost of penalty for late registration of shares during the three months ended March 31, 2006. The shares and warrants were re-valued at March 31, 2006, and the result of this re-valuation was to increase the value of the shares by $52,423 and to decrease the value of the warrants by $6,868. These decreases were credited to other (income) expense during the three months ended March 31, 2006. At March 31, 2006, the fair value of the common stock issuable under the penalty for late registration of shares is $2,186,549, and the fair value of the warrants issuable under the penalty for late registration of shares is $476,662. These amounts appear as current liabilities on our condensed consolidated balance sheet at March 31, 2006.

We attempted to register the shares and warrants by filing a registration statement with the Securities and Exchange Commission on November 24, 2004, and amended this registration statement with pre-effective amendments no. 1, 2, 3 and 4 on July 20, 2005, November 16, 2005, February 22, 2006 and April 7, 2006, respectively. On July 10, 2006 we, pursuant to Rule 477 of Regulation C of the Securities Act of 1933, as amended, applied for an order granting the immediate withdrawal of its Registration Statement on Form SB-2.

In August 2006, we reached an agreement with the investors in the private placement of October 2004 which limits the number of warrants and shares which we are obligated to issue pursuant to the penalty calculation to an aggregate of 18% of the number of original number of shares and warrants issued in the October 2004 private placement. This agreement limits the number of shares and warrants issuable pursuant to the penalty calculation to an aggregate of 4,150,798 shares and warrants to purchase an additional 1,634,400 shares, respectively. This resulted in a decrease in the number of share issuable 2,475,107 (with a fair value of $816,785) and a decrease in the number of warrant shares of 974,587 (with a fair value of $177,789). This resulted in a net realized gain of $994,574 during the three months ended June 30, 2006.

In August 2006, we issued 4,150,798 shares and warrants to purchase 1,634,400 shares and relieved accrued liabilities in the aggregate amount of $1,053,904.

For the twelve months ended December 31, 2006 we marked to market the value of the shares and warrants issuable pursuant to the penalty calculation for an aggregate gain in the amount of approximately $445,673 and $123,505, respectively.

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Liquidity And Capital Resources

At March 31, 2007, we had current assets of $2,231,654 consisting of cash of $2,124,695 and other current assets of $106,959. At March 31, 2007, we also had current liabilities of $471,008, consisting of accounts payable and accrued liabilities of $421,008 and notes payable of $50,000. This resulted in net working capital at March 31, 2007 of $1,760,646. During the three months ended March 31, 2007, the Company used cash in operating activities of $621,404. From the date of inception (October 30, 2002) to March 31, 2007, the Company has had a net loss of $14,146,539 and has used cash of $6,615,346 in operating activities.

At December 31, 2006, we had current assets of $2,831,502 consisting of cash of $2,752,103 and prepaid services of $79,399. Also, at December 31, 2006, we had current liabilities of $510,969, consisting of accounts payable and accrued liabilities of $460,969 and notes payable of $50,000. This resulted in working capital of $2,320,533. During the twelve months ended December 31, 2006, we used cash in operating activities of $2,035,484. From the date of inception (October 30, 2002) to December 31, 2006, we had a net loss of $13,285,180 and used cash of $5,993,942 in operating activities. We met our cash requirements from our inception through December 31, 2006 via the private placement of $7,877,901 of our common stock and $908,628 from the issuance of notes payable, net of repayments.

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 March 31, 2007 via the private placement of $7,877,901 of our common stock and $908,628 from the issuance of notes payable, net of repayments.

Since our inception, we have been seeking additional third-party funding. During such time, we have retained a number of different investment banking firms to assist us in locating available funding; however, we have not yet been successful in obtaining any of the long-term funding needed to make us into a commercially viable entity. During the period from October 2004 to March 2007, we were able to obtain financing of $9,097,736 from a series of private placements of our securities (which resulted in net proceeds to us of $7,877,901). . During the period from October 2004 to December 2006, we were able to obtain financing of $9,097,736 from a series of private placements of our securities (which resulted in net proceeds to us of $7,877,901). Based on our current plan of operations all of our current funding is expected to be depleted by the end of January 2008. 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.

In December 2006, we completed a private placement, whereby we sold an aggregate of $5,482,600 worth of units to accredited investors. In consideration of the investment, we granted to each investor certain registration rights and anti-dilution rights. We have agreed that not before 180 days after the closing of the private placement and not later than 190 days thereafter, that we shall file with the SEC an appropriate registration statement to register these shares along with the shares underlying these warrants. In the event that we fail to comply with the filing deadline, there shall be a 1% penalty for each 30 day period (or pro rata portion thereof) paid to each investor in cash or additional shares. This penalty amounts to an aggregate of 342,662 shares and 171,331 warrants per 30 day period until such a time as a registration statement that includes these shares and warrants is filed or 12 months. As of December 31, 2006, we are not subject to any penalty.

On August 1, 2006, we converted two cash advances into unsecured senior promissory notes bearing interest at the rate of 12% per annum, in the respective amounts of $50,000 and $20,000. These notes were entered into with

individual accredited investors, one of whom was a Director. Following the payment of fees and expenses, we received net proceeds of approximately $68,600. On October 6, 2006, principal and interest of $733 was returned on the $20,000 note.

In July 2006, we received a cash advance from a Director in the amount of $25,000 to be used as an upfront payment for a radiation study. This advance bears interest at the rate of 12% per annum. This cash advance was not used, as no upfront payment was required, and subsequently, principal and interest of $370 was returned on August 30, 2006.

On July 25, 2006, we entered into an unsecured senior promissory note bearing interest at the rate of 12% per annum in the amount of $250,000 with an accredited investor. Following the payment of commissions and expenses, the Company received net proceeds of approximately $210,000. On October 6, 2006 principal and interest of $5,583 was returned.

In June 2006, we issued 5,000 shares of common stock for cash of $450 pursuant to the exercise of a warrant at $0.09 per share.

In June 2006, we issued a note payable in the amount of $9,750 in exchange for consulting services. This note bears interest at the rate of 7% per annum. In addition to the note payable, the consulting agreement calls for the issuance of 695,000 common stock purchase warrants if certain milestones are met. The warrants expire five years from the date of issuance and have an exercise price of $0.32. On October 11, 2006, principal and interest of $237 was returned.

On April 13, 2006, we entered into an unsecured senior promissory note bearing interest at the rate of 12% per annum in the amount of $500,000 with an accredited investor. Following the payment of commissions and expenses, we received net proceeds of approximately $439,875 On October 6, 2006 principal and interest of $28,500 was returned.

On July 25, 2006, we entered into an unsecured senior promissory note in the amount of $250,000 with an accredited investor. Following the payment of commissions and expenses, the Company received net proceeds of approximately $210,000.

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

Pursuant to our employment agreement with John Fermanis, our Chief Financial Officer, dated February 15, 2005, we paid a salary of $60,000 until the company completed a financing of $500,000 or more. This occurred on March 4, 2005 when the company completed a tender offer for warrants totaling $1,211,000 net of fees. From March 4, 2005, until December 31, 2005, we paid an annual salary of $85,000. Thereafter, we paid an annual salary of $98,000 for the second year ending December 31, 2006 and will pay 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.

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Pursuant to our employment agreement with Hal N. Siegel, our Senior Director of Product Development and Regulatory Affairs, dated October 23, 2006, we will pay an annual base salary of $200,000 for the first year and $210,000 for the second year. Mr. Siegel will also be eligible for discretionary bonuses under the Company's stock option plan during his employment. In addition, Mr. Siegel received options with a term of five years to purchase 200,000 shares of common stock of the Company. The options are exercisable at $0.20 per share. The employment agreement has a term of two years, subject to early termination provisions. Upon termination of Mr. Sigel's employment by the Company without cause or constructive termination, as defined in the agreement, the Company agrees to pay to Mr. Siegel the remainder of his salary for the year or six months salary, whichever is greater, and any accrued vacation.

Pursuant to the terms of the change of control agreement, the Company agrees to pay Mr. Siegel his salary for a period of 18 months from the date an involuntary termination, payable in accordance with the Company's compensation practice. Involuntary termination is defined as the termination of Mr. Siegel's employment by Company without cause or due to constructive termination at any time within one-year from a change of control event, as defined in the agreement.

While we have 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.

Our independent certified public accountants have stated in their report included on our annual report on SEC Form 10-KSB filed with the Securities and Exchange Commission on April 17, 2007 and Form 10-KSB/A filed with the Securities and Exchange Commission on April 30, 2007 that we have incurred a net loss and negative cash flows from operations of $1,486,046 and $2,035,484, respectively, for the year ended December 31, 2006. During the three months ended March 31, 2007, we used cash in operating activities of $621,404 and had a net loss of $861,359. From the date of inception (October 30, 2002) to March 31, 2007, we had a net loss of $14,146,539 and has used cash of $6,615,346 in operating activities.

This loss, in addition to a lack of operational history, raises substantial doubt about our ability to continue as a going concern. In the absence of significant revenue and profits, and since we do not expect to generate significant revenues in the foreseeable future, we, in order to fund operations, will be completely dependent on additional debt and equity financing arrangements. There is no assurance that any financing will be sufficient to fund our capital expenditures, working capital and other cash requirements for the fiscal year ending December 31, 2007. No assurance can be given that any such additional funding will be available or that, if available, can be obtained on terms favorable to us. If we are unable to raise needed funds on acceptable terms, we will not be able to develop or enhance our products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, we will not be able to continue operations.

Until such time, if at all, as we receive adequate funding, we intend to continue to defer payment of all of our obligations which are capable of being deferred, which actions have resulted in some vendors demanding cash payment for their goods and services in advance, and other vendors refusing to continue to do business with us. 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 we have sufficient to meet or operating needs through January 2008. Thereafter, we believe that we will require at least an additional $500,000 to meet our expenses over the next 12 months.

Inflation

Our opinion is that inflation has not had a material effect on our operations.

Off-Balance Sheet Arrangements

There were no off-balance sheet arrangements as of March 31, 2007.

Acquisition or Disposition of Plant and Equipment

We acquired $32,397 worth of property, plant or equipment for the year ended December 31, 2006. We did not dispose or acquire any significant property, plant or equipment during the first quarter ended March 31, 2007. We do not anticipate the sale of any significant property, plant or equipment during the next twelve months.

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BUSINESS

Overview

IR BioSciences Holdings, Inc. is a development stage biotechnology company. Through our wholly-owned subsidiary ImmuneRegen BioSciences, Inc., we are engaged in the research and development of potential drug candidates, Homspera™ and its derivatives, Radilex™ and Viprovex™. We defined Radilex and Viprovex as derivatives of Homspera due to the potential difference in formulations and indications for use of such compounds. Our goal is to develop these potential drug candidates to be used as possible countermeasures for homeland security threats, including radiological, chemical and biological agents, such as influenza and anthrax. We hope there may exist not only a market for products related to biodefense through governmental purchasing, but there also may exist a potential commercial market for treatments of cancer treatment side-effects and seasonal influenza.

Our patents, patent applications and continued research are derived from discoveries made during research studies related to the function of Substance P, which is found in the body and has a large number of actions. These studies were funded by the Air Force Office of Scientific Research (AFOSR) in the early 1990s and were conducted by research scientists, including our co-founders Drs. Mark Witten and David Harris. In the course of research on Substance P, these scientists created a number of synthetic analogues, structural derivatives with slight chemical differences, for study. One of these, which we have named Homspera, is the basis for our drug development efforts and our intellectual property. 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. There can be no assurance that our interpretation of the results of our studies will prove to be accurate after further testing and our beliefs regarding the potential uses of our drug candidates may never materialize.

Our current focus is on the development of two potential formulations derived from Homspera, Radilex and Viprovex.

We are researching Radilex for use as a potential treatment for acute exposure to radiation. To date we have sponsored seven studies and co-sponsored three studies all of which were conducted utilizing rodents. The results of these studies suggest Radilex may play a role in increased survival among tested rodents following exposure to lethal doses of gamma radiation. We believe that Radilex, if developed, may be an acceptable candidate to be marketed to governmental agencies for procurement. Further, we believe that a commercial market may exist for the use of Radilex as it relates to the treatment of radiation-induced side effects of cancer treatments, either as a stand alone treatment or as a co-therapeutic agent to be used with other therapies.

Viprovex is being researched by us for use in potential treatments of exposure to biological agents, such as infectious disease, which include influenza and anthrax. Based on early studies on Homspera and existing literature on Substance P, we are researching the efficacy of Viprovex as a potential treatment for exposure to chemical agents, such as formalin. To date we have sponsored three studies related to the treatment of influenza, three on the exposure to anthrax spores and one on exposure to formalin. We believe the results of these studies indicated potential efficacy in the use of Viprovex as both a stand alone treatment and an adjuvant, to be used in conjunction with other drugs. If Viprovex can be developed, we believe that potential applications may exist for sale to governments for the treatment of exposure to anthrax and pandemic influenza. In addition, we believe that potential commercial opportunities may exist for the treatment of seasonal influenza and other viral or bacterial infections, either as a stand-along drug or as an adjuvant to other existing drugs.

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 the potential use of Radilex in the treatment of acute radiation syndrome and the other for the potential use of Viprovex in the treatment of avian influenza.

We have filed patent applications and provisional patent applications, for the use of Homspera and derivatives thereof. We own four registered patents, two issued U.S. and two issued foreign patents. We also have 39 pending patents, comprised of three pending Patent Cooperation Treaty (PCT) applications, ten pending U.S. provisional patent applications and 26 pending foreign provisional patent applications.

Our potential drug candidates, Radilex and Viprovex, are at early, pre-clinical stages of development and may not be shown to be safe or effective and may never receive regulatory approval. Neither Radilex nor Viprovex have yet been tested in large animals or 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 such testing is permitted, none of Radilex, Viprovex or any other potential drug candidates, if any, derived from Homspera may be successfully developed or shown to be safe or effective.

The results of our pre-clinical studies and clinical trials may not be indicative of future clinical trial results. A commitment of substantial resources to conduct time-consuming research, pre-clinical studies and clinical trials will be required if we are to develop any commercial applications using Homspera or any derivatives thereof. Delays in planned patient enrollment in our future clinical trials may result in increased costs, program delays or both. None of our potential 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.

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SUBSTANCE P AND HOMSPERA™

Our patents, patent applications and continued research are derived from discoveries made during research studies related to the function of Substance P, which is found in the body and has a large number of actions. These studies were funded by the Air Force Office of Scientific Research (AFOSR) in the early 1990s and were conducted by research scientists, including our co-founders Drs. Mark Witten and David Harris. In the course of Substance P research, scientists created for study a number of analogues, or structural derivatives with slight chemical differences, of Substance P. One of these analogues of Substance P, which we have termed Homspera, is the basis for our research and development of potential drug candidates.

Substance P

The elements carbon, oxygen, nitrogen and hydrogen can be combined to form amino acids, a basic building block of life. When amino acids are combined through a specific biochemical process they form what are called peptides or proteins. Proteins play a number of fundamental roles in living organisms, from structural to messaging between cells. When components of the nervous system use chemicals to transmit signals between nerves and brain cells to propagate signaling throughout the body, those chemicals are called neurotransmitters. When peptides are released by nerve cells or other cells and effect or modulate this neurotransmission, they are termed neuropeptides.

One such neuropeptide is Substance P. Substance P is a relatively small peptide made of just eleven amino acids. Substance P was discovered in 1931 and found to have local blood-pressure reducing effects. The peptide is difficult to isolate, and consequently was ignored for tens of years. When science developed to the point that peptides could be recognized by their amino acid structures, Substance P was one of the first identified. The amino acid sequence (using the standard three-letter acronyms for amino acids) of Substance P is presented below:

Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Gly-Leu-Met-NH_2.

Neuropeptides, such as Substance P, were originally identified as being distributed throughout the peripheral and central nervous systems of experimental animals, and then of humans. To date, Substance P has also been shown to be produced in non-neuronal cells such as human endothelial cells, Leydig cells, enterochromaffin cells, epithelial cells, fibroblasts, keratinocytes, intestinal and airway smooth muscle cells, inflammatory and immune cells, and in cells of the female reproductive system.

In early research Substance P was revealed as playing a key role in the transmission of pain. Later on, Substance P was identified as being involved in the pathophysiology of psychiatric disorders, like anxiety and depression. Additionally, Substance P has been shown to be involved in a number of physiological processes, such as blood vessel and smooth muscle contractions, and in the levels and responses of the cells of the blood and immune system.

Substance P produces this wide variety of effects by acting through three different molecular receptors, located on the surface membrane of sensitive cells. These receptors are called NK1, NK2 and NK3 receptors, and binding of Substance P to one receptor subtype or another will cause different chemical signaling to occur both inside and outside cells. These receptor binding differences are believed to be responsible for the different physiological results following the stimulation of the different receptor subtypes.

Homspera

Within a few years following the discovery of the amino acid sequence of Substance P, numerous synthetic analogues were being produced in an attempt to better understand how the structure and function of the molecule were related. One particular analogue was produced by the replacement of the amino acid glycine (Gly) with Sarcosine (Sar or

N-methyl glycine) at the ninth position and the introduction of oxidized methionine (Met(O_2)) in place of methionine (Met) at the eleventh position. The resulting peptide, still 11 amino acids long, but now with a slightly different molecular weight, is thus called Sar^9, Met $(O_2)^{11}$-Substance P. The amino acid sequence for Homspera is presented below:

Arg-Pro-Lys-Pro-Gln-Gln-Phe-Phe-Sar-Leu-Met(O_2)-NH_2.

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It is these specific chemical alterations that are presumably responsible for the different physiological actions of Homspera versus endogenous Substance P. In fact, Sar^9, Met $(O_2)^{11}$-Substance P was first synthesized in an attempt to make chemicals that had specific distinctions in their activity from that of the parent Substance P molecule.

Homspera, or Sar^9, Met $(O_2)^{11}$-Substance P differs from Substance P in at least two ways. It is reported to be active at only the NK1 receptor, and to be more resistant to the enzyme that usually breaks down Substance P and thereby terminates its action. Thus Sar^9, Met $(O_2)^{11}$-Substance P is both more specific than Substance P, and also more persistent in the body.

In December 2004 we filed an application with the US Patent and Trademark Office in an effort to trademark the name Homspera to refer to Sar^9, Met $(O_2)^{11}$-Substance P for its potential usage in a number of applications. Our application is still pending.

Radilex™ and Viprovex™

We use the trade names Radilex and Viprovex to differentiate these derivatives of Homspera. The active ingredient, Homspera, is chemically equivalent in both Radilex and Viprovex; however, since both Radilex and Viprovex are to be used in differing potential treatments, and thus have different indications for use, we anticipate that we will formulate them differently in the future to support appropriate (and possibly different) modes of administration. For this reason, we have created the trade names to more easily differentiate the potential formulations, and thus applications, with respect to their development and potential future market opportunities.

In the early AFOSR studies, it was observed that the exposure of animals to JP-8 jet fuel resulted in pathological changes in the lungs and immune systems of those exposed. Homspera was administered to the test animals after prolonged exposure to the jet fuel. Based on the results of these studies, we believe that the administration of Homspera prevented some of the harmful effects of the jet fuel exposure in the lungs, as well as having a positive effect on the immune system. However, there is no guarantee that our interpretation of the results of these studies will prove to be accurate after further testing.

Based on our interpretation of these results, our current focus is on the development of two potential drug applications, Radilex and Viprovex.

We are researching Radilex for use as a potential treatment for acute exposure to radiation. To date we have sponsored seven studies and co-sponsored three studies all of which were conducted utilizing rodents. We believe the results of these and other studies suggest Radilex may play a role in increasing an individual's ability to overcome the effects of radiation, and, in the cases of exposure to potentially lethal radiation, to play a role in increased rates of survivability. Based on the sum of these studies, we believe that Radilex, once and if developed, could be an acceptable candidate to be purchased by governmental agencies for national distribution in the event of a significant nuclear or radiological threat. Further, we believe that a commercial market may exist for the use of Radilex as it relates to the treatment of radiation-induced side effects of cancer treatments, either as a stand alone treatment or as a co-therapeutic agent to be used with other treatments.

Viprovex is being researched by us for use in potential treatments of exposure to biological agents, such as anthrax and infectious diseases, including influenza. Based on early studies on Homspera and existing literature on Substance P, we are also researching Viprovex as a potential treatment for exposure to chemical agents, such as formalin. Formalin, a highly toxic chemical, is a solution of formaldehyde gas dissolved in water and used industrially. To date we have sponsored three studies related to the treatment of influenza, three on the exposure to anthrax spores and one on exposure to formalin. We believe the results of these studies indicated potential efficacy in the use of Viprovex as both a stand alone treatment and to be used in conjunction with other drugs. If Viprovex can be developed, we believe

that potential applications may exist for sale to governments for the treatment of exposure to anthrax and pandemic influenza. In addition, we believe that potential commercial opportunities may exist for the treatment of seasonal influenza and other viral or bacterial infections, either as a stand-alone drug or in conjunction with other existing drugs.

Applications

Our initial pre-clinical applications that we are researching are in the treatment of the effects on the body caused by (i) exposure to radiation (Radilex);(ii) infectious disease and harmful biological materials (Viprovex); and, (iii) harmful chemical agents (Viprovex). In addition to these three potential applications, we continue to explore the potential capabilities of Homspera and strive to better understand the mechanisms of this compound in order to further our development efforts with regard to not only our current application research, but also potential future applications.

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To date we have sponsored seven radiation studies and co-sponsored three radiation studies all of which were conducted utilizing rodents. We have sponsored three studies on the potential treatment of anthrax exposure and one study on avian influenza all of which were conducted utilizing rodents. We have also sponsored one chemical study in an attempt to determine initial indications of efficacy on the treatment of formalin exposure.

All our product candidates are in the pre-clinical stage of development. They have only been introduced to FDA via the pre-IND filings, submissions to which the FDA offers no judgment thereon. To date we have been issued two Pre-Investigational New Drug (PIND) numbers by the U.S. Food & Drug Administration (FDA) - one for the potential use of Radilex in the treatment of acute radiation syndrome and one for the potential use of Viprovex in the treatment of avian influenza. The table below illustrates our current product candidates and their current stage of development within the FDA approval process.

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

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."

RADILEX

All of our product candidates based on Radilex are in the pre-clinical stage of development. On January 14, 2004, we received a Pre-Investigational New Drug Application (PIND) number for the use of Radilex (PIND No. 63,255) in the treatment of acute radiation syndrome.

To date we have sponsored seven radiation studies and co-sponsored three radiation studies all of which were conducted utilizing rodents to study dose response to radiation, the impact on survival and to distinguish survival response using different forms of drug delivery. In each of these studies mice were exposed to varying levels of radiation.

Radiation is emitted electromagnetic energy. Excessive exposure to ionizing radiation over a short period of time, as is the case in nuclear or radiological attacks, leads to the development of radiation sickness, or Acute Radiation Syndrome (ARS). Exposure to lower doses of radiation may, either by design or as a side effect of cancer treatment, result in the destruction of bone marrow cells responsible for maintaining the levels of red blood cells, white blood cells and platelets, which are vital for the transport of oxygen and waste products; for immunity and disease/infection fighting ability; and for the formation of blood clots, respectively. Hence, destruction results in compromised oxygen carrying capacity, diminished immune system function, and uncontrollable bleeding.

Certain bone marrow cells are called hematopoietic stem cells, and they can multiply and mature into precursor cells to the B-cells and T-cells of the immune system, or into precursors of the red blood cells or of the granulocytes and macrophages, which are also of the immune system, and megakaryocytes, which produces platelets. Thus all circulating cells of the immune system, red blood cells and platelets derive from these stem cells.

In studies to date we have collected data that we believe suggests that Radilex shows efficacy in treating ARS by combating neutropenia and thrombocytopenia, which is the decrease in blood levels of white blood cells and platelets, the major medical conditions associated with acute exposure to radiation. Loss of these cells results in increased sensitivity to infection and to uncontrolled bleeding, both of which can be potentially life-threatening. Further, as treatment for cancer often includes radiation treatment, we believe that the potential also exists for Radilex to be used for cancer patients as a stand alone treatment or a co-therapeutic agent to be used with other drugs as treatment.

Data collected in studies performed at the Oak Ridge National Laboratory in 2006, we believe, revealed that Radilex not only prolonged survival of animals exposed to lethal gamma irradiation, but also appeared to have increased platelet concentrations in surviving animals.

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There is also preliminary research data showing that the activity of a specific enzyme (poly-(ADP-ribosyl) polymerase, or PARP), may be responsible for repairing DNA that has been damaged by radiation can be modified by Substance P. When damage is severe, the activation of this enzyme becomes too much for the cell to support, and the cell triggers its own destruction. The chain of events that result in this destruction is called apoptosis, a process of deliberate life termination that a cell undergoes following exposure to high levels of stress, and agents that can control the rate of apoptosis are of significant importance in controlling the functioning of organs and organisms. If a cell can be kept alive long enough to repair cellular damage, it might be of more value to the organism.

Based on the above referenced, and other, data, for example, claiming Substance P itself is anti-apoptotic, we believe that one possible mechanism by which Radilex is able to prolong survival in animal models (either in addition to its effect on stem cells or perhaps as a mechanism by which it impacts stem cells), is by modulating the activities of the PARP-1 enzyme within cells. By possibly preventing cells from dying, Radilex may be effective in treating the impact of cell radiation, thereby decreasing the likelihood of death.

Further, we believe that our survival data from irradiated mice studies and mechanistic studies in cell culture have shown indications of hematopoietic stem cell replenishment of circulating leukocytes and platelets, which could be of value in radiation-treated cancer patients as well as other blood cell depleting conditions.

Acute total body irradiation exposure studies have been performed at the University of Arizona Cancer Center and at Oak Ridge National Laboratories (ORNL). These studies show that radiation destroys the immune system resulting in pneumonia and death, and that Radilex, we believe demonstrates efficacy at reversing the loss of white blood cells that comprise the immune system, as well as platelets necessary to control blood clotting, subsequently leading to an increase in survival rates.

Continuing radiation studies are expected to be performed at TGen Drug Development Services (TD2, the drug development arm of Translational Genomics Research Institute (TGen)), Pacific Northwest National Laboratory, and Stem Cells Technology Inc. to further explore the impact of radiation on the hematopoietic system of Radilex-exposed animals. In addition, future studies will be designed to examine mechanistic indicators at both high levels of radiation where Radilex has shown protection, as well as at lower levels. If successful, these studies would demonstrate the ability of Radilex to address both the government market, as a countermeasure to radiological dispersion devices, such as dirty bombs or nuclear explosions, as well as the cancer market, as an adjuvant treatment candidate potentially ameliorating the side effects resulting from cancer radiotherapy.

We are also in discussions with LAB Research Inc. and Bridge Pharmaceuticals to conduct an efficacy study in a whole body gamma irradiation model in non-human primates utilizing Radilex. To date, we have discussed protocols and received price quotations from LAB Research.

We believe these animal studies provide support for our continued effort to research and develop Radilex to treat the effects of exposure to radiation. However, there is no assurance that our interpretation of the results of the studies will prove to be accurate after further testing.

VIPROVEX

All of our product candidates based on Viprovex are in the pre-clinical stage of development. We are researching the efficacy of Viprovex as a potential treatment, either as a stand alone application or as co-therapeutic treatment, for exposure to various biological agents, such as infectious disease, including influenza and anthrax. We are also researching the efficacy of Viprovex as a potential treatment for exposure to chemical agents, such as formalin. Formalin, a highly toxic chemical, is a solution of formaldehyde gas dissolved in water and used industrially.

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Biological Exposure Applications

Infectious Disease - Seasonal and Pandemic Influenza

We believe that results from our studies may reveal the potential ability of Viprovex to enhance flu therapies, minimize the respiratory impact of influenza infection and augment the capability of vaccination to induce a protective immune response.

In October 2003 the AFOSR sponsored preliminary studies with the Hong Kong influenza virus (A/Hong Kong/8/68) and Viprovex at the University of Arizona, Arizona Health Sciences Center, Lung Injury Laboratory. We believe that these studies suggest that when mice were exposed to the irritant JP-8 jet fuel and then inoculated with the Hong Kong respiratory virus (HKV), they experience elevated levels of inflammatory cells in their lungs. These levels were reduced in animals also treated with Viprovex. In contrast to control animals exposed to the virus, the JP-8 treated animals also treated with Viprovex did not develop the clinical symptoms of viral infection, which included increases in alveolar macrophages and neutrophils in broncho-alveolar lavage fluid. These cells are components of the immune system that are expressed out of the blood and into the fluid inside the lungs coating the alveoli. The alveoli, found in the respiratory zone of the lungs, are primary sites of gas exchange where blood and air exchange oxygen and carbon dioxide carried by red blood cells.

Animals treated with Viprovex also exhibited lower levels of leukotriene B4 (LTB4), a chemical released by white blood cells during an immune response, than animals not treated with Viprovex. Elevated LTB4 would attract the inflammatory cells, particularly neutrophils, which would follow infection with virus. Electron micrographs showed healthier, normal appearing cells in the airways with 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 attack, engulf and destroy the virus more effectively. Without virus particles in the lungs, there would be no need to mount an immune response. Based on the results of this study, we believe that Viprovex may be potentially used to increase the ability of the body's own immune system to naturally fight off flu strains. We believed this opened up the possibility that Viprovex could be used either as a stand alone treatment or as an adjunct to a vaccine or other therapy.

On November 29, 2005 we applied for a PIND from the Department of Health and Human Services (HHS) for the use of Viprovex in the treatment of avian influenza. The PIND number for the use of Viprovex in treating avian influenza was issued on December 19, 2005 (PIND No. 73,709).

Subsequently, we have sponsored three influenza studies conducted at Virion Systems, Inc, one of which is still ongoing, utilizing rodents to test the efficacy of Viprovex in treating the avian influenza A/Wuhan/359/95 (H3N2), a model system for studying the H5N1 avian influenza.

In our opinion, the data acquired to date in examining the effect of Viprovex on influenza infection suggests an anti-viral action occurs in lungs and, more noticeably, in nose. Further, in conjunction with the suggested anti-viral effect, animal weights and temperatures were normalized. Differences in cytokines (small peptide signaling molecules released by cells of the immune system to mediate inflammation and immune responses) such as certain interleukins and interferons were also witnessed. In the opinion of management, such Viprovex-induced changes in immune response as evinced by cytokine signals and decreased viral titers in lung and nose demonstrate the potential efficacy of Viprovex. Based on our results, we believe that Viprovex may show efficacy as a stand alone drug in the treatment of influenza. Further, when used in conjunction with a neuraminidase inhibitor, currently the most effective pharmacological agents (zanamivir (Relenza®, GlaxoSmithKline) and oseltamivir (Tamiflu®, Roche) are neuraminidase inhibitors) to treat influenza (by inhibiting an enzyme necessary for infectivity), Viprovex might be an effective adjuvant therapeutic on treating or preventing influenza.

There is no assurance that our interpretation of the results of the studies will prove to be accurate after further testing.

Anthrax

Anthrax is an often-fatal human disease resulting from infection of the bacterium *Bacillus anthracis*. Anthrax is most often contracted by skin to skin, or cutaneous, contact with an infected lesion, resulting from the handling of infected animal products. Cutaneous anthrax has a mortality rate of roughly 20%. In contrast, the inhalation of *B. anthracis* spores results in a significantly more severe and lethal infection, with mortality rates of greater than 80%. As a result of the high mortality rate and route of infection, anthrax is considered a prominent agent of bioterrorism.

To date we have sponsored three anthrax studies all of which were conducted utilizing rodents to determine if Viprovex will reduce the mortality rate of an active infection of pulmonary anthrax. In our opinion, when treated with Viprovex prior to exposure to anthrax spores, Viprovex elicited protective, prophylactic efficacy and when treated a short time period after exposure to anthrax spores, Viprovex elicited therapeutic efficacy.

In 2006 we completed a series of studies with Hyperion Biotechnology Inc. at their laboratory facilities located at Brooks City-Base in San Antonio, Texas. The purpose of these studies was to determine if Viprovex could reduce the mortality rate of an active infection of pulmonary anthrax. The first of these studies was initiated in October 2005. This research indicated, in our opinion, that Viprovex offers protection from anthrax exposure in a mouse model. In these studies, we witnessed mice treated with Viprovex to exhibit a dose-dependent, increased survival rate 11 days post-exposure to anthrax spores. Additionally, based on this research, we believe Viprovex to elicit a dose-dependent prophylactic protection from anthrax in a mouse model.

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Further research, in our opinion, has supported these findings of prophylactic efficacy of Viprovex against anthrax and also demonstrated Viprovex to show efficacy in increasing survival rates in mice pretreated with anthrax. Additionally, while these results are preliminary, we believe that Viprovex, when used as an adjuvant, could play an important role, in conjunction with other therapies, in improving treatments of anthrax exposure.

There is no assurance that our interpretation of the results of the studies will prove to be accurate after further testing.

Other Infectious Diseases

Melioidosis, also called Whitmore's disease, is an infectious disease caused by the bacterium *Burkholderia pseudomallei*, and is endemic to Southeast Asia and is seen in the South Pacific, Africa, India, and the Middle East as well. The causative agent, *Burkholderia pseudomallei* can be transmitted from animals to man as well as from person to person. The bacteria can be found in contaminated water and soil and is spread to humans and animals through direct contact with the contaminated source. Mortality rate for melioidosis varies and is as high as 90% particularly when aerosolized. The Centers for Disease Control and Prevention (CDC) considers both *B. pseudomallei* and its related *B. mallei* as potential agents for biological warfare and biological terrorism.

In March 2007, we began the first of a series of studies to investigate the therapeutic effects of Viprovex on acute melioidosis. These studies are to be performed in conjunction with Singapore's Defense Medical & Environmental Research Institute, DSO National Laboratories ("DSO"). The studies are to be funded by DSO and are expected to be completed during the third quarter of 2007.

Chemical Exposure Applications

Based on early studies on Homspera and existing literature on Substance P, we are researching the efficacy of Viprovex as a potential treatment for exposure to chemical agents, such as formalin. Formalin is a solution of formaldehyde gas dissolved in water, used industrially and toxic typically via crosslinking of proteins to other nearby proteins. To date, we have only conducted limited preclinical studies with regard to the development of Viprovex for indications related to treatment of exposure to harmful chemicals.

JP-8 Jet Fuel and Smoke

We believe our early AFOSR rodent studies demonstrated the administration of Substance P and Homspera to animals exposed to JP-8 decreased the immune system effects, while administration of Substance P antagonists compounded the deleterious effects. Further experiments performed using Viprovex examined effectiveness in preventing lung injury on inhalation of toxic fumes. In our opinion based on our results, Viprovex has been shown to exhibit anti-inflammatory effects in animal models.

There is no assurance that our interpretation of the results of the studies will prove to be accurate after further testing.

Formalin

Formaldehyde is one of the 25 most abundantly produced chemicals in the world and has use in many industries. When dissolved in water at 30% to 50% formaldehyde, and often with methanol as a stabilizer, the resulting formalin solution is toxic to embryos and adult organisms.

We have conducted one pilot study to determine if aerosolized Viprovex could be efficacious in attenuating lung injury after formalin exposure.

In rats exposed to an aerosol application of formalin data suggests, in our opinion, that treatment with Viprovex may minimize lung damage concurrent with formalin inhalation.

There is no assurance that our interpretation of the results of the studies will prove to be accurate after further testing.

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ADJUVANT THERAPEUTIC

Results from studies also suggest that Homspera may also have potential value as an adjuvant, co-therapeutic agent or as a vaccine adjuvant. Adjuvants are unique among active ingredients in drugs in that they are designed to not stimulate an immune response against themselves, but they are required to augment the immune response against other, co-administered compounds. Studies of Homspera co-administered with anti-viral vaccines show immune-enhancing adjuvant activity. Studies performed in animal models of influenza and acute radiation syndrome have revealed the potential capability of Homspera to enhance the action of approved anti-viral medications as well as to provide adjunctive impact on anti-tumor radiation therapy.

Mechanistic studies in cell culture have revealed elevations in components of what is the most basic aspect of the immune system, termed the innate immune system, that are consistent with activation of specific cell components called Toll-like Receptors, a postulated mechanism by which some vaccine adjuvants increase immune responses to vaccine components. Additionally, the anti-anthrax activity reported by Homspera is similarly consistent with activation of components of innate immunity that have been reported to have anti-anthrax activity, such as defensins, small peptides found in immune cells that help destroy invading bacteria.

The potential efficacy of Homspera as a vaccine adjuvant likely results from the unique mechanism through which Homspera modulates the immune system. The actions of Homspera are presumably mediated predominately through interactions with the Neurokinin-1 receptor (NK1-R). Indeed, cells treated with Homspera show large elevations in the messaging molecules that signal defensin production, but Homspera does not seem to activate TLRs directly.

Vaccine adjuvant studies with Homspera are currently being carried out by GenPhar Inc. These studies are being conducted to examine the impact of vaccination with pieces of influenza viruses (a current H5N1 "avian influenza" strain and from the 1918 Spanish Influenza virus). We believe preliminary data suggests that Homspera elevated host immune responsiveness above that induced by vaccine alone system.

Based on outside research on Substance P and our study results witnessed to date, we believe that our results, although only preliminary, indicate that Homspera may demonstrate adjuvant capabilities, and thus be capable of augmenting host immune system responsiveness to vaccines for diseases such as pandemic avian influenza, seasonal influenza, and perhaps others for which vaccines exist or are under development.

We believe that there is also potential for Homspera to be used as a co-therapy to what is called adjuvant therapy for cancer patients, as secondary treatment often involves radiation treatments following chemotherapy, in an attempt to kill more of the cancer cells. Survival data from gamma-irradiated mice studies have shown indications of hematopoietic stem cell replenishment of circulating leukocytes and platelets, which could be of value in radiation-treated cancer patients. There is no assurance that our interpretation of the results of the studies will prove to be accurate after further testing.

POTENTIAL FUTURE PIPELINE APPLICATIONS

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

To date, we have filed use patent applications in multiple jurisdictions, inside and outside of the U.S., for use of the active ingredient in Homspera for: treatment of avian influenza in mammals, use as an adjuvant to enhance response

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

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DEVELOPMENT PROGRAM

Research and Development Spending

Due to our liquidity and limited cash available our spending on research and development activities has been limited. We spent approximately $484,029 and $237,005 in 2006 and 2005, respectively, in research and development activities related to the development of Radilex and Viprovex as protectants against the effects of biological and radiological/nuclear threats. From our inception in October 2002, we have spent $1,026,597 in research and development activities. These costs only include the manufacture and delivery of our drug by third party manufacturers, 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 salary for Dr. Siegel, have been classified in officer salaries for consistency of financial reporting.

We anticipate that during the next 12 months we will increase our research and development spending to a total of approximately $700,000 in an effort to further develop Radilex and Viprovex. This research and development cost estimate includes additional animal pharmacology studies, formulation and animal safety/toxicity studies. If we receive additional funds, through either investment funding or grants, we expect we will increase our research and development spending.

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.

Since our incorporation in October 2002, we have made submissions for eleven grants either by submitting Requests For Information (RFI), Requests for Proposal (RFP), Broad Agency Announcements (BAA), requests for white papers and/or fully executed grant applications. To date our applications for grant funding have not been accepted. We intend to continue to apply for grants; however, there can be no assurance that we will ever receive any grants.

Animal Efficacy Rule

Using traditional efficacy studies in the development of some of our potential applications would require healthy human volunteers to be exposed to lethal agents and pathogens. This cannot be done. Therefore, we intend to apply for approval based upon a 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 rule, in situations where it would be unethical to conduct traditional 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. Under either the animal efficacy rule or traditional efficacy rules, 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.

Contract Research Organizations (CRO) and Collaborators

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) and collaborative relationships.

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

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Collaborators and Contractors who we have already worked with or are implementing a program with are described below.

- University of Arizona College of Medicine, Tucson, Arizona. We have sponsored or co-sponsored seven mouse radiation studies and co-sponsored one inhalation study at the University of Arizona College of Medicine, Tucson, Arizona since January, 2005. In addition, the Air Force Office of Scientific Research, AFOSR, has sponsored additional studies at the University of Arizona College of Medicine utilizing Homspera, Radilex and Viprovex.

    - Hyperion Biotechnology Inc. Hyperion Biotechnology performs research programs in the areas of probiotics, biomarker discovery, infectious disease and human performance enhancement. We have contracted a series of anthrax studies with Hyperion testing Viprovex as a potential treatment to anthrax infection. These studies are conducted by Hyperion at its research facility located on the U.S. Air Force School of Aerospace Medicine (USAFSAM) campus in Brooks City-Base in San Antonio, Texas. To date we have completed three studies on anthrax. Hyperion has also conducted mechanistic studies in cell culture looking at cellular mechanisms impacted by Homspera. These studies are ongoing.

- St. Joseph's Hospital and Medical Center (Phoenix, Arizona). St. Joseph's has performed assays on Homspera for us on a sub-contracting basis.

- Battelle Memorial Institute's Medical Research and Evaluation Facility (MREF) (Columbus, Ohio). Battelle has issued a letter of intent to support us in our testing of Homspera as an Avian Influenza therapeutic in mice. Battelle is actively involved in analytical development studies through activities at PNNL and studies protocols are in development for avian influenza studies that may be initiated at Battelle.

- Pacific Northwest National Laboratory (Richland, Washington). PNNL has issued a letter of intent to support us in our testing of Homspera as a Universal Protectant therapeutic. In addition to ongoing analytical studies at PNNL and managed by Battelle, additional studies regarding radiation and influenza in both small animals and non-human primates, are under discussion and protocols are being developed.

- Oak Ridge National Laboratory (Oak Ridge, Tennessee). We have contracted with Oak Ridge to conduct Proof of Concept mouse radiation studies that began in February, 2006 and to help facilitate additional pre-clinical and future clinical trials with regard to testing Radilex for potential uses to treat the effects of acute radiation. To date, we have completed three studies that have confirmed experimental results obtained previously and have expanded insight into radioprotection dosing and mechanisms.

- PanFlu LLC and Virion Systems, Inc. We have contracted with PanFlu and Virion to conduct influenza studies to test the efficacy of Viprovex in treating the avian influenza A/Wuhan/359/95 (H3N2), a model system for studying the H5N1 avian influenza. To date two completed studies have provided evidence that we believe suggests viral reduction by Viprovex and provided preliminary evidence for potential mechanisms. Planned studies include a co-treatment study with the neuraminidase inhibitor oseltamivir (Tamiflu®, Roche).

- TGen (Translational Genomics Research Institute) Drug Development Services (TD2 LLC) (Phoenix, Arizona). We have contracted with TD2 to perform anti-cancer research designed to assess preclinical safety and efficacy (with the ability to expand to Phase 1 and Phase 2a clinical studies at the associated Mayo Clinic Scottsdale, MD Anderson Cancer Center and Arizona Cancer Center Tucson). A broad spectrum of Preclinical Studies are ongoing at TD2, including cancer screening against established cell lines and chemo-therapeutics, analytical assay development, radioprotection studies in small animals and non-GLP safety and pathology studies.

    - AAIPharma. We have contracted with AAIPharma to do analytical development work.

- GenPhar, Inc. We have contracted with GenPhar to perform adjuvant studies in mice in conjunction with their vaccine platform technology.

- Covance - Generation of antibodies and development of an assay to determine Homspera concentrations in blood.

- Singapore's Defense Medical & Environmental Research Institute, DSO National Laboratories. We have contracted with Singapore's Defense Medical & Environmental Research Institute, DSO National Laboratories to perform a series of studies to investigate the therapeutic effects of Viprovex on acute melioidosis. The first in the series of studies began in March 2007.

- We are also in discussions with LAB Research Inc. and Bridge Pharmaceuticals to conduct an efficacy study in a whole body gamma irradiation model in non-human primates utilizing Radilex. To date, we have discussed protocols and received price quotations.

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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 two outside consultants related to the research and development, including regulatory affairs, of our potential products.

Kelly McQueen, MD, MPH, PLLC was engaged in July 2005 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. Dr. 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. Dr. McQueen 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). Dr. McQueen's contract with us provides for cash compensation on an hourly basis and reimbursement for travel and expenses. The original term of the agreement was until October 2005 but has been mutually agreed to have been extended on the same terms on a month by month basis.

Dr. Jack Caravelli, Ph.D. was contracted in November 2005 to provide advisory services in support of our initiative to commercialize radiation sickness treatments, bio-defense applications and countermeasures. He is presently a senior advisor for the Threat Reduction Cooperation with the Office of Policy at the U.S. Department of Energy (D.O.E.). Dr. Caravelli's contract provides for cash compensation at an hourly rate and reimbursement for any related travel and expenses. The original term of the agreement was until January 2006 but has been mutually agreed to have been extended on the same terms on a month by month basis.

Advisory Boards

We currently have two advisory boards - the Scientific Advisory Board and the Bioterrorism Preparedness Advisory Board. 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 Scientific Advisory Board was formed to educate and provide direction with regard to the discovery, research and development of applications using Homspera in the areas of expertise of the various advisory board members. The following individuals comprise our Scientific Advisory Board:

Dr. John Dann, M.D., D.D.S. Dr. Dann is a graduate of Harvard University Dental School and Washington University Medical School. He is a Board Certified maxillofacial and cranial facial surgeon.

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

Sarah A. Kagan, J.D., Ph.D. Sarah Kagan is a partner in the Banner & Witcoff, Ltd., an intellectual property legal firm in Washington, D.C. Dr. Kagan holds a Ph.D. degree in molecular biology from the University of Wisconsin (1981) and a J.D. degree from George Washington University (1988). Dr. Kagan’s professional memberships include the American Bar Association, Women’s Bar Association of the District of Columbia, and the American Intellectual Property Law Associations.

Susan E. Leeman, Ph.D. Dr. Leeman is a Professor in the Department of Pharmacology and Experimental Therapeutics at the Boston University School of Medicine. Dr. Leeman was one of the first scientists to isolate substance P in the central nervous and gastrointestinal systems. Dr. Leeman was elected to the National Academy of Sciences in 1991.

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

Akihiro Shimosaka, Ph.D. Dr. Shimosaka has extensive domestic and international experience in consulting early and later stage biotechnology companies in research and development, product development and regulatory issues.

Dr. Hal Siegel Ph.D., Dr. Siegel has two decades of experience providing scientific, clinical and regulatory assistance to life science client companies across the medical product spectrum, helping them meet business needs and FDA requirements from pre-clinical studies through the regulatory submission process and into the post-approval marketplace. Dr. Siegel is a member of our Board of Directors and serves as our Senior Director, Product Development and Regulatory Affairs.

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

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

Frederick M. Burkle, Jr., M.D., Director, Asia-Pacific Center for Biosecurity, Disaster & Conflict Research, and a Professor in Tropical Medicine, Public Health and Epidemiology, at the University of Hawaii's John A. Burns School of Medicine, Senior Fellow, the Harvard Humanitarian Initiative and Director of the Asia-Pacific Branch and Senior Scholar, Scientist, and Visiting Professor at John Hopkins University Medical Institutes' Center for Refugee & Disaster Response.

Jack Caravelli, Formerly Senior Advisor to the Department of Energy for Threat Reduction Cooperation

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

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

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.

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

John Kalns Ph.D.: Vice President and Chief Scientific Officer Hyperion Biotechnology, Inc. at Brooks City-Base.

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

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

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MANUFACTURING

As previously discussed, we expect 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 other potential products, if any, that may be derived from Homspera.

We have used and expect to continue to use third party manufacturers to obtain synthetic Homspera or Sar^9, Met $(O_2)^{11}$-Substance P, the active ingredient in experimental formulations of Radilex and Viprovex. We believe Sar^9, Met $(O_2)^{11}$-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 Sar^9, Met $(O_2)^{11}$-Substance P is readily available from various sources, and several suppliers are capable of supplying such in both clinical and initial commercial quality and quantities.

Since to date 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 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.

We have filed patent applications and provisional patent applications for the use of Sar^9, Met $(O_2)^{11}$-Substance P, the active ingredient in Homspera, Radilex and Viprovex. The intellectual property owned by us, as further described below, is for various potential uses of Sar^9, Met $(O_2)^{11}$-Substance P. We own four patents, comprised of two issued U.S. and two issued foreign patents. We also have 39 pending patents relating to the use of Sar^9, Met $(O_2)^{11}$-Substance P. These pending patents are comprised of three pending Patent Cooperation Treaty (PCT) applications, ten pending U.S. provisional patent applications and 26 pending foreign provisional patent applications. 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 Sar^9, Met $(O_2)^{11}$-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 jurisdictions, 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 treatment of avian influenza in mammals, use as an adjuvant to enhance response to a vaccine, reducing the risk or severity of anthrax infection, treatment of blood cell depletion, 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 inchoate.

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In March of 2007, our patent attorneys completed a Freedom to Operate Search conducted for freedom to use Sar^9, Met $(O_2)^{11}$-Substance P as a medicament for treatment/prevention of avian influenza in mammals; wound healing stimulation, especially in irradiated persons; enhancing response to a vaccine (i.e. as an adjuvant); and immunostimulation of immunocompromised individuals. The results of the Freedom to Operate Search uncovered no obstacles or blocks to practice these fields of use. However, 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.

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 and the assignments have been recorded with the USPTO. Some of our research has been funded by the Air Force Office of Scientific Research and has been 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 entitled “Substance P Treatment for Immunostimulation” which includes the treating of cancer and the stimulating of the maturation of a juvenile immune system and the treatment of viral or bacterial infection, and the reduction of risk of cancer. 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 four registered patents, two issued U.S. and two issued foreign patents. We also have 39 pending patents, comprised of three pending Patent Cooperation Treaty (PCT) applications, ten pending U.S. provisional patent applications and 26 pending foreign provisional patent applications. The assignment documents are included as Exhibits.

Registered Patents:

Title	**Country**	**Registration No.**
Substance P Treatment for Immunostimulation	United States of America	5,998,376
Substance P Treatment for Immunostimulation	United States of America	5,945,508
Substance P Treatment for Immunostimulation	Australia	737201
Substance P Treatment for Immunostimulation	Canada	0957930
	Switzerland	0957930
	Germany	0957930
	Spain	0957930
	France	0957930
	United Kingdom	0957930
	Ireland	0957930
	Italy	0957930
	Liechtenstein	0957930
	Monaco	0957930

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Patents Pending:

Title	**Country**	**Application No**.
Prevention of Respiratory Infections in Fowl	Patent Cooperation Treaty	PCT/USO5/42601
Treatment of Skin Diseases	Patent Cooperation Treaty	PCT/US05/45369
Treatment for Asthma	Patent Cooperation Treaty	PCT/US06/11833
Method to Promote Wound Healing	United States of America	tba
Amelioration of Effects of Cigarette Smoke	United States of America	10/645839
Stimulation of Hair Growth	United States of America	10/539734
Acute Respiratory Syndromes	United States of America	10/553232
Inducing and Maintaining Hair Color	United States of America	tba
Anti-Aging Effects of Substance P	United States of America	tba
Method to Reduce the Risk and/or Severity of Anthrax Infection	United States of America	60/828723
Method to Treat Blood Cell Depletion	United States of America	60/809391
Prophylactic and Therapeutic Treatment of Mammals for Avian Influenza Infections	United States of America	60/866901
Use of Homspera (substance P analog) as an adjuvant	United States of America	60/885562
Method to Promote Wound Healing	Australia	tba
Method to Promote Wound Healing	Canada	tba
Method to Promote Wound Healing	European Patent Office	tba
Method to Promote Wound Healing	Japan	tba
Prevention of Respiratory Infections in Fowl	Singapore	200500467-6
Prevention of Respiratory Infections in Fowl	Thailand	97659
Prevention of Respiratory Viral Infection in Fowl	Vietnam	1-2005-00599
Treatment of Skin Diseases	Singapore	200500466-8
Treatment of Skin Diseases	Vietnam	1-2005-00598
Treatment of Skin Diseases	Thailand	98080
Treatment of Asthma	Singapore	200504104-1
Amelioration of Effects of Cigarette Smoke	Singapore	200501072-3
Amelioration of Effects of Cigarette Smoke	China	3820184.4
Amelioration of Effects of Cigarette Smoke	Japan	2004-532943
Amelioration of Effects of Cigarette Smoke	European Patent Office	3791722.6
Amelioration of Effects of Cigarette Smoke	Canada	2496447
Amelioration of Effects of Cigarette Smoke	Vietnam	1-2005-00215
Acute Respiratory Distress Syndrome	Hong Kong	6107144.4
Acute Respiratory Syndrome	European Patent Office	4759500.4
Acute Respiratory Syndromes	Singapore	200507608-8
Medicaments for Treating or Protecting SARS or ARDS	Vietnam	1-2005-01560
Anti-Aging Effects of Substance P	Japan	tba
Anti-Aging Effects of Substance P	Canada	PCT/US05/13113

Anti-Aging Effects of Substance P	European Patent Office	5755488.3
Anti-Aging Effects of Substance P	China	tba
Anti-Aging Effects of Substance P	Australia	2005240026

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

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

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

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

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

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

We also rely on trade secrets and unpatentable know-how that we seek to protect, in part, by confidentiality agreements. It is our policy to require our employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to

be kept confidential and not disclosed to third parties except in specific limited circumstances. We also require signed confidentiality or material transfer agreements from any company that is to receive our confidential information. In the case of employees, consultants and contractors, the agreements generally provide that all inventions conceived by the individual while rendering services to us shall be assigned to us as our exclusive property. There can be no assurance, however, that these agreements 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 for all of our potential applications and no assurance can be given that patents do not exist or could not be filed which would have an adverse affect on our ability to market our products or maintain our competitive position with respect to our products. If our technology components, devices, designs, products, processes or other subject matter are claimed under other existing U.S. or foreign patents, or are otherwise protected by third party proprietary rights, we may be subject to infringement actions. In such event, we may challenge the validity of such patents or other proprietary rights or we may be required to obtain licenses from such companies in order to develop, manufacture or market our products. There can be no assurances that we would be able to obtain such licenses or that such licenses, if available, could be obtained on commercially reasonable terms. Furthermore, the failure to either develop a commercially viable alternative or obtain such licenses could result in delays in marketing our proposed products or the inability to proceed with the development, manufacture or sale of products requiring such licenses, which could have a material adverse affect on our business, financial condition and results of operations. If we are required to defend ourselves against charges of patent infringement or to protect our proprietary rights against third parties, substantial costs will be incurred regardless of whether we are successful. Such proceedings are typically protracted with no certainty of success. An adverse outcome could subject us to significant liabilities to third parties and force us to curtail or cease our development and sale of our products and processes.

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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.

Trademarks

On December 9, 2004 we filed for trademarks with US Patent and Trademark Office (USPTO) for Homspera, Radilex and Viprovex.

On August 15, 2006, Viprovex became a federally registered trademark (Reg. No. 3,130,407) in International Class 5 for pharmaceutical products, namely antidotes for the treatment of viral, chemical and biological warfare agents.

On October 17, 2006, opposition to the Homspera mark was filed by another pharmaceutical company that distributes an anti-viral compound under a name which they claim has a “similar sound and appearance.” The matter is currently being negotiated and we have granted an extension of the opposition term.

On December 5, 2006, the Trademark Office issued a Notice of Allowance to our Intent-to-Use (ITU) trademark application for Radilex as biopharmaceuticals, namely products for counteracting exposure to radiation and chemical agents. As of the date of this report, the time for opposition to the Radilex mark has expired.

On January 9, 2007, the Trademark Office issued a Notice of Allowance of our Intent-to-Use (ITU) trademark application for ImmuneRegen for biotechnology pharmaceuticals, namely adjuvants, counteractants and immunostimulant products for enhancing the natural and reactive immunity to toxic agents.

RESEARCH AND LICENSE AGREEMENTS

Our patents and continued research on Sar^{9}, Met $(O_2)^{11}$-Substance P are derived from discoveries made during research studies funded by the Air Force Office of Scientific Research (AFOSR) in 1994 by our co-founders Drs. Mark Witten and David Harris. In December 2002 we entered into consulting agreements on a month-to-month basis with Dr. Mark Witten and Dr. David Harris. Under the terms of these agreements, Drs. Witten and Harris 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 Drs. Witten and Harris a non-refundable fee of $5,000 per month. We and Dr. Harris agreed to terminate the consulting agreement for Dr. Harris in March 2005. In January 2006, the company received correspondence from Dr. Witten stating that he would terminate his consulting contract if his specific requirements were not met. We subsequently accepted his termination effective February 1, 2006.

In December 2002, we entered into a royalty-free license agreement with Drs. Witten and Harris. Under the terms of the license agreement, Drs. Harris and Witten granted to us an exclusive license to use and sublicense certain patents, medical applications, and other technologies developed by them. Our obligations under this agreement include (i) reasonable efforts to protect any 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.

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GOVERNMENTAL REGULATION

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

REGULATORY PROCESS IN THE UNITED STATES

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

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

Regardless of how our product candidates are regulated, the FFDCA and other Federal statutes and regulations govern or influence the research, 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 process required by the FDA before a new drug or biologic may be marketed in the United States generally involves the following:

§ completion of pre-clinical laboratory tests or trials and formulation studies;

§ submission to the FDA of an IND for a new drug or biologic, which must become effective before human clinical trials may begin;

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

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

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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:

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

Phase III: These are commonly referred to as pivotal studies. If a product is found to have an acceptable safety profile and to be potentially effective in Phase II clinical trials, new clinical trials will be initiated to further demonstrate 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 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 rule, in situations where it would be unethical to conduct traditional Phase III efficacy studies in humans, as is the case with our applications relating to the treatment of maladies caused by exposure to various chemical and biological agents, the FDA will review new drugs for approval on the basis of safety in humans and efficacy in relevant animal models. . Under either the animal efficacy rule or traditional efficacy rules, 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.

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.

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

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

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

ONGOING FDA REQUIREMENTS

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

The labeling, advertising, promotion, marketing and distribution of a drug or biologic product also must be in compliance with FDA and FTC requirements which include, among others, standards and regulations for

direct-to-consumer advertising, industry-sponsored scientific and educational activities, and promotional activities involving the internet. The FDA and FTC have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a Warning Letter directing the company to correct deviations from regulatory standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA and enforcement actions that can include seizures, injunctions and criminal prosecution.

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

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

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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 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.

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. and Cleveland Biolabs, 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.

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

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

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

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

EMPLOYEES

From our inception through June 11, 2007, we have relied and continue to rely on the services of outside consultants for services and currently have seven total employees, five full-time employees and two part-time employees. Our full-time employees are Michael K. Wilhelm, our Chief Executive Officer; John N. Fermanis, our Chief Financial Officer; Hal N. Siegel, Ph.D., Senior Director, Product Development and Regulatory Affairs, Chris Romano, Scientific Associate; and, the fifth 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 12 months.

If we are able to expand our operations, we will incur additional costs for personnel. This projected increase in personnel is dependent upon our generating revenues and obtaining sources of financing. There is no guarantee that we will be successful in raising the funds required or generating revenues sufficient to fund the projected increase in the number of employees.

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

None of our employees are covered by collective bargaining agreements, and we believe our relations with our employees are favorable.

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DESCRIPTION OF PROPERTY

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

LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS

The following tables set forth certain information with respect to our directors and officers as of June 11, 2007. The following persons serve as our directors and executive officers.

Name	Age	Position
Michael K. Wilhelm	40	President, Chief Executive Officer and Director
John N. Fermanis	53	Chief Financial Officer
Hal N. Siegel, Ph.D.	53	Sr. Director of Product Development and Regulatory Affairs and Director
Theodore E. Staahl, M.D.	62	Director
Robert J. Hariri, M.D., Ph.D.	48	Director
Lance K. Gordon, Ph.D.	59	Director

Mark L. Witten, Ph.D. resigned as a member of the Board of Directors on May 18, 2006.

Background of Executive Officers and Directors.

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 Corp. 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 retains the title of Managing Director of Foresight Capital Partners but the company has had limited and insignificant business operations since December 2002.

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

Hal N. Siegel, Ph.D., Sr. Director of Product Development and Regulatory Affairs and Director. Dr. Siegel has served on our Board of Directors since June, 2006 and was appointed Senior Director of Product Development and Regulatory Affairs of the Company in October, 2006. Dr. Siegel first came to ImmuneRegen from Siegel Consultancy, which has been providing 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 science client companies developing drugs, therapeutic biologics, combination products, traditional devices, and in vitro diagnostic products. Dr. Siegel previously provided strategic and tactical management consulting services to a start up software company making knowledge management and collaboration tools for regulated life science companies, as well as Sun Microsystem’s Global Life Science group, working with sales, marketing, business development, legal and professional services groups. His degrees are from Rensselaer Polytechnic Institute and SUNY Buffalo (Ph.D., Biochemical Pharmacology).

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.

Robert J. Hariri, M.D., Ph.D., Director. Dr. Hariri, M.D. has served on our Board of Directors since April 2007. Dr. Hariri has been CEO of a division of Celgene since 2005. Previously, he had been President of the division from 2002 to 2005. The division focuses on human stem and biomaterial solutions for a range of clinical indications. From 1998 to 2002, prior to joining Celgene, Dr. Hariri was Founder, Chairman and Chief Scientific Officer for Anthrogenesis Corp./LIFEBANK, Inc., a New Jersey-based privately held biomedical technology and service corporation involved in umbilical cord blood banking and its supporting technology platform. LIFEBANK is one of the largest cord blood bank companies and is recognized as a technological leader in the industry From 1987 to 1994, he was Co-founder, Vice Chairman and Chief Scientific Officer of Neuordynamics, a privately held medical device and technology corporation. While there, he led the design, testing and development of several medical device technologies. He also arranged and negotiated initial private seed investment and private placement with Johnson & Johnson, Inc. Dr. Hariri has held academic positions at Cornell University Medical College Cornell University Graduate School of Medical Sciences. He has also played a prominent medical role at Cornell University Medical College, The New York Hospital-Cornell Medical Center and The Jamaica Hospital-Cornell Trauma Center. While at Cornell, he was the Director of The Center for Trauma Research. He received his Medical Degree and Ph.D from Cornell University and was awarded a Bachelor of Arts Degree from Columbia College.

Lance K. Gordon, Ph.D., Director. Dr. Gordon has served on our Board of Directors since May 2007. He is an accomplished corporate executive with extensive experience leading biopharmaceutical companies focused on the development, manufacture and commercialization of biologic products for the prevention and treatment of human infectious disease. Dr. Gordon has served as President, Chief Executive Officer and as a Director of VaxGen, Inc. from 2001 to 2007 during which time, the Company generated over $250 million in income and $1 billion in contracts for biodefense vaccines. Prior to joining Vaxgen, Dr. Gordon was Executive Director of North America for Acambis plc. and a member of the Company's Board of Directors from 1999 to 2001. Previously, he was President and CEO of OraVax, Inc. from 1990 to 1999, prior to its acquisition by Peptide Therapeutics to form Acambis. Before joining OraVax, he was the CEO of North American Vaccine from 1988 to 1990, prior to its acquisition by Baxter International. He has also held positions as Associate Director, Clinical Pharmacology at E. R. Squibb and Research Director, Viral and Bacterial Vaccines, at Connaught Laboratories. Among his many Professional Affiliations, Dr. Gordon is a member of the United States National Vaccines Advisory Committee (NVAC) since 2005, a member of the Sabin Vaccine Institute Board of Trustees since 2003 and a member of the Expert Panel of the Meningitis Vaccine Project, WHO and PATH since 1999. He received his Ph.D. in Biomedical Science, Immunology and Molecular Genetics from the University of Connecticut at Farmington and was awarded a Bachelor of Arts Degree from the University of California at Humboldt.

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FAMILY RELATIONSHIPS

Our executive officers are appointed by and serve at the discretion of our Board of Directors. There are no family relationships between any director and/or any executive officer.

EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth information concerning the compensation for the two fiscal years ended December 31, 2006 and 2005, of our principal executive officer, our two most highly compensated executive officers other than our principal executive officer whose annual compensation exceeded $100,000, and up to two additional individuals for whom disclosure would have been made in this table but for the fact that the individual was not serving as an executive officer of our company at December 31, 2006, if any (collectively, the "Named Executive Officers").

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Stock Awards ($)	Option Awards ($)	All Other Compensation ($)(2)	Total ($)
Michael K. Wilhelm							
President, CEO and	2006	$286,317	$41,278	—	$735,731	—	$1,063,326
Director	2005	$275,000	$28,870	—	$82,912	—	$386,782
John N. Fermanis	2006	$98,000	$17,596	—	—	—	$115,596
Chief Financial Officer	2005	$85,000	$4,590	$76,416	—	—	$166,006
Hal N. Siegel							
Senior Director, Product Development and							
Regulatory Affairs and	2006	$42,308	—	—	$32,071	$95,574	$169,953
Director	2005	—	—	—	—	$58,285	$58,285

(1) The amounts shown are the amounts of compensation cost recognized by us in fiscal year 2006 related to the issuance of common stock purchase warrants as bonus in fiscal year 2006 and prior fiscal years.

(2) The amounts shown are the amounts of compensation cost recognized by us in fiscal year 2006 related to the issuance of common stock purchase warrants in fiscal year 2006 and prior fiscal years.

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STOCK OPTIONS

As of June 11, 2007, we have issued 6,014,212 stock options at a weighted average exercise price of $0.26, of which 5,951,000 are at an average price of $0.23 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. At June 11, 2007, of this amount 974,495 stock options remain unvested. There are 10,472,493 shares reserved for future grant under our 2003 Stock Option, Deferred Stock and Restricted Stock Plan.

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) if the Internal Revenue Code, nonstatutory stock options (collectively, the "Stock Options") and awards of restricted stock and deferred stock and to sell shares of our common stock ("Common Stock") pursuant to the exercise of such stock options to executive officers, together with our other employees, 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. On June 28, 2006, our shareholders voted to approve an amendment to our 2003 Stock Option, Deferred Stock and Restricted Stock Plan to increase the number of shares of our Common Stock reserved and available for issuance under the Plan from 3,600,000 to 20,000,000. As of June 11, 2007 we have 6,014,212 stock options outstanding.

Option Grants in Fiscal Year 2006

In July 2006, we granted options to purchase 1,896,970 shares of common stock to our Chief Executive Officer, Michael K. Wilhelm. The options vest 50% after ninety days of continued employment and the balance in equal monthly installments for 12 months thereafter.

In September 2006, we issued options to purchase 3,500,000 shares of common stock to our Chief Executive Officer, Michael K. Wilhelm. The options vest 50% after thirty days of continued employment with the balance in equal monthly installments for 12 months thereafter.

In October 2006, we issued options to purchase 200,000 shares of common stock to our Senior Director, Product Development and Regulatory Affairs and Director, Hal N. Siegel.

As of December 31, 2006, total unrecognized stock-based compensation expense related to stock options was $264,274. During the year ended December 31, 2005 we charged $296,394 to operations related to recognized stock-based compensation expense for employee stock options.

Every 30-day period, options to purchase a total of 224,874 shares of common stock held our president and chief executive officer vest. During the three months ended March 31, 2007, options to purchase a total of 782,570 shares of common stock held by our president and chief executive officer were vested. As of June 11, 2007, options to purchase a total of 899,495 shares of common stock held our president and chief executive officer remain unvested.

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Employment Agreements

President and Chief Executive Officer:

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 option to purchase 2,000,000 shares of our common stock at an exercise price equal to the fair market value per share on the date option is granted.

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

Chief Financial Officer:

Pursuant to our employment agreement with John Fermanis, our Chief Financial Officer, dated February 15, 2005, we paid a salary of $60,000 until we completed a financing of $500,000 or more. This occurred on March 4, 2005 when we 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 also receives 100,000 shares of our common stock, which are earned at the rate of 1/12 or 8,333 per month beginning January 2005.

Senior Director of Product Development and Regulatory Affairs:

Pursuant to our two-year employment agreement with Hal N. Siegel, our Senior Director of Product Development and Regulatory Affairs, dated October 23, 2006, we will pay an annual base salary of $200,000 for the first year and $210,000 for the second year. Mr. Siegel will also be eligible for discretionary bonuses under our stock option plan during his employment. In addition, Mr. Siegel received options with a term of five years to purchase 200,000 shares of our common stock. The options are exercisable at $0.20 per share. Upon termination of Mr. Sigel's employment by us without cause or constructive termination, as defined in the agreement, we agree to pay to Mr. Siegel the remainder of his salary for the year or six months salary, whichever is greater, and any accrued vacation. Pursuant to the terms of the change of control agreement, we agree to pay Mr. Siegel his salary for a period of 18 months from the date an involuntary termination, payable in accordance with our compensation practice.

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Outstanding Equity Awards at Fiscal Year-End as of December 31, 2006

As of the year ended December 31, 2006, the following Named Executive Officers had the following outstanding equity awards:

	Option Awards					
Name	Number of Securities Underlying Unexercised Options # Exercisable	Number of Securities Underlying Unexercised Options # Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)		Option Exercise Price ($)	Option Expiration Date
Michael K. Wilhelm	1,222,416	—	674,554	$	0.231	7/14/2011
President, CEO and	279,299	—	175,246	$	0.220	9/13/2011
Director	1,871,304	—	1,174,151	$	0.220	9/13/2011
John N. Fermanis Chief Financial Officer	—	—	—		—	—
Hal N. Siegel Senior Director, Product Development and Regulatory Affairs and Director	200,000	—	—	$	0.200	10/23/2011

Director Compensation

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Mark L. Witten, Ph.D. (1)	$ 5,000	--	--	--	--	--	$ 5,000

(1) Mark L. Witten, Ph.D. resigned as a member of the Board of Directors on May 18, 2006. On December 16, 2002 we entered into a consulting agreement with Mark Witten, our chief research scientist and director. The consulting agreement was entered into on a month-to-month basis. Under the terms of this agreement, Dr. Witten agreed to place at our disposal 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. This contract was terminated effective February 1, 2006.

(2)

Subject to approval by the State of Arizona of our 2003 Stock Option, Deferred Stock and Restricted Stock Plan (the "2003 Stock Option Plan"), we will grant to Dr. Gordon and Dr. Hariri under the Company's 2003 Stock Option Plan, a non-qualified stock option to purchase 1,000,000 shares of common stock at an exercise price per share equal to 85% of the fair market value on the date of the grant approval to vest immediately.

Compensation of Directors

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

Other Arrangements. We may from time to time issue options and/or warrants to executives and directors for fulfilling certain performance goals.

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CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

DIRECTOR INDEPENDENCE

As we are quoted on OTCBB and not one of the national securities exchanges, we are not subject to any director independence requirements. With the exceptions of Theodore E. Staahl, M.D., Robert J. Hariri, M.D., Ph.D. and Lance K. Gordon, Ph.D., none of our present directors qualifies as an independent director pursuant to Rule 10A-3 promulgated under the Exchange Act due to their affiliation with us as employees. Our Board of Directors determined that Mr. Staahl, Mr. Hariri and Mr. Gordon are "independent," as that term is defined by the NASDAQ Stock Market.

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 former Director and co-founder, Mark Witten. IR BioSciences Holdings, Inc. holds less than 1% ownership in the company.

ImmuneRegen Asia has not conducted any business since its creation in May 2004. On March 23, 2006, per shareholder and Board approval, ImmuneRegen Asia was struck off the register of companies and dissolved. A notice of such action was published in the Governmental Gazette on April 7, 2006.

Officer Bonus

Michael K. Wilhelm, our President and Chief Executive officer, received an incentive bonus of $82,239 in cash per the terms of his employment agreement.

Related Party Loans

There were no loans to related parties entered into during the fiscal year ended December 31, 2006. Additionally, there were no loans to related parties outstanding at December 31, 2006.

Cash Advances

In July 2006, the Company received a cash advance from a director in the amount of $25,000. This advance bears interest at the rate of 12% per annum. The Company repaid this cash advance on August 30, 2006 plus accrued interest in the amount of $370.

Credit Cards

The Company has a line of credit with Bank of America for $25,000. Our Chief Executive Officer Michael Wilhelm co-signs this line of credit. At year end December 31, 2006 the Company had an outstanding balance on the credit card of $21,373.

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Consulting Agreements

On December 16, 2002 we entered into a consulting agreement with research scientist, Mark L. Witten, Ph.D., who was one of our two founders. The consulting agreement was on a month-to-month basis. Under the terms of these agreements, Dr. Witten agreed 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 him 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.

Pursuant to consulting agreement entered into with Dr. Witten during the period from October 30, 2002 (inception) to December 31, 2002, we accrued $2,500 in consulting fees. During the period from January 1, 2003 to December 31, 2003, we accrued an additional $60,000 in consulting fees. We had accrued payables collectively due to Dr. Witten of $62,500 and $2,500 as of December 31, 2003 and 2002, respectively. In connection with our 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.

License Agreements

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

In February 2005, Dr. Witten executed assignment documents in which, for good and valuable consideration, patent applications and patents developed by him 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. Dr. Witten have also assigned all proprietary technology developed at ImmuneRegen subsequent to the execution of the February 2005 assignment documents.

The termination of Dr. Witten's consulting agreement in February 2006 does not have any impact on the license agreement.

Outstanding Loans

At December 31, 2006, we have outstanding one note payable in the amount of $50,000 to a Director. This note bears interest at the rate of 12% per annum. This note matures in July 2007 at which time principal and accrued interest are due.

We believe that our arrangements with all related parties are at fair market value and are on terms comparable to those that would have been reached in arms' length negotiations had the parties been unaffiliated at the time of negotiations.

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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 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.

Our directors sign an indemnification agreement to provide substantial protection against personal liability and to provide them with specific contractual assurance that the protection promised by the Bylaws and Certificate of Incorporation will be available to them regardless of, among other things, any amendment to or revocation of such Bylaws and Certificate of Incorporation or any change in the composition of the Company’s Board of Directors or any acquisition transaction relating to the Company.

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 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.

PRINCIPAL AND SELLING STOCKHOLDERS

This prospectus relates to the resale from time to time of up to a total of 57,480,548 shares of common stock by the selling stockholders, comprising:

- 40,347,423 shares of our common stock that were issued to selling stockholders pursuant to transactions exempt from registration under the Securities Act of 1933; and
- 17,133,125 shares of common stock underlying warrants that were issued to selling stockholders pursuant to transactions exempt from registration under the Securities Act of 1933.

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The following table sets forth certain information as of June 11, 2007 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 June 11, 2007 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 114,322,539 shares of common stock outstanding as of June 11, 2007.

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:

- Robert J. Hariri, M.D., Ph.D. has served as a member of our Board of Directors since April 2007; and,

- 5,482,600 shares being registered hereunder are owned by registered representatives of Joseph Stevens & Co., Inc. and are being registered hereby per certain registration rights granted to them for participation in our private offering in December 2006.

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.

	Number of Shares of Common stock Beneficially Owned Prior to Offering (1)(3)		**Percentage of Shares of Common Stock Beneficially Owned Prior to the Offering (4)**	**Number of Shares of Common Stock Registered for Sale Hereby**	**Number of Shares of Common Stock Beneficially Owned After Completion of the Offering (2)**	**Percentage of Shares of Common Stock Beneficially Owned After Completion of the Offering (4)**
Named Executive Officers and directors (2):						
Michael K. Wilhelm	9,219,041	5	7.6%	0	9,219,041	7.6%
John N. Fermanis	180,000	6	*	0	180,000	*
Hal N. Siegel, Ph.D.	249,900	7	*	0	249,900	*
Theodore Staahl, M.D.	3,446,464	8	3.0%	0	3,446,464	3.0%

Robert J. Hariri, M.D., Ph.D.	960,545	9	*	937,500	23,045	*
Lance K. Gordon, Ph.D.	0		*	0	0	*
All directors and executive officers as a group (4 persons)	14,055,950	10	11.5	937,500	13,118,450	10.7

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Owners of 5% or more:

Mark Witten 1501 N. Campbell Avenue Room 3352 Tucson, AZ 85724	8,900,778	11	7.7%	0	8,900,778	7.7%

Selling Stockholders:

Wayne K. Adams 4845 Campo Sano Ct. Coral Gables, FL 33146	300,000	13	*	300,000	0	*
Yombo Aderinto 5651 Rockledge Drive Buena Park, CA 90621	56,250	14	*	56,250	0	*
Daniel Anderson 4409 Willow Creek Circle Bellbrook, OH 45305	93,750	15	*	93,750	0	*
Jan Arnett Longwood Road Sandspoint, NY 11050	234,375	16	*	234,375	0	*
The Bahr Family L.P. 41 Cooke Street Providence, RI 02906	234,375	16	*	234,375	0	*
The Henry H. Bahr QTIP Trust D/T/D 2/22/88 41 Cooke Sreet Providence, RI 02906	234,375	16	*	234,375	0	*
Lauren Banjany 73 Rita Lane Jackson, NJ 08527	55,000	12	*	55,000	0	*
Paul J. Bargiel PC Employees Pension Plan & Trust D/T/D 06/01/1986 100 West Monroe Ste 902 Cook Co Chicago, IL 60603	496,875	17	*	496,875	0	*

Delaware Charter Guarantee & Trust Co. F/B/O Paul F. Berlin IRA R/O 230 W. Superior Street Suite 510 Chicago, IL 60610	468,750	18	*	468,750	0	*

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Louis A. Best & Madeline M. Best JTWROS 10120 Greensward Link Ijamsville, MD 21754	93,750	15	*	93,750	0	*
Mohanlal Bhagwansingh & Leelautee Bhagwansingh JT WROS 113 Crest Camp Fyzabad Trinidad & Tobago	140,625	19	*	140,625	0	*
Tom Bleile 961 Fair Rd. Norwalk, OH 44857	206,250	20	*	206,250	0	*
Lester B. Boelter 50 Shady Oak Court Winona, MN 55987	2,140,625	21	1.9%	1,640,625	500,000	*
Delaware Charter Guarantee & Trust Co. F/B/O Roger Bradshaw R/O IRA P.O. Box 284 Candler, FL 32111	356,250	22	*	356,250	0	*
David Briskie 15006 Beltway Drive Addison, TX 75001	334,375	16	*	234,375	100,000	*
Keith Buhrdorf 4582 South Ulster Street Suite 1303 Denver, CO 80237	796,875	23	*	796,875	0	*
Roy M. Cappadona 341 Boniface Parkway Unit H Anchorage, AK 99504	93,750	15	*	93,750	0	*
George L. Cartagena & Martha Cartagena JT TEN Carr 125 KM 1.3 Camino C Bosques Aquadilla, PR 00603	234,375	16	*	234,375	0	*

Edward L. Chant 226 Edward Street Suite 200 Aurora, Ontario L4G 3S8 Canada	498,750	18	*	468,750	30,000	*

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Daniel A. Claps 360 Lightner Avenue Staten Island, NY 10314	40,000	12	*	40,000	0	*
Robert Clauss 9923 Clark Street Clive, IA 50325	281,250	24	*	281,250	0	*
Jeremy Cohen 331 Franklin St. Brownville, NY 13615	110,000	12	*	110,000	0	*
Guy C. Collins 653 Grissom Parkway Myrtle Beach, SC 29577	150,000	25	*	150,000	0	*
Buck Core 162 W. Cedar Drive Chandler, AZ 85248	93,750	15	*	93,750	0	*
Robert Costomoris 305 Lexington Ave., Apt. #2B New York, New York 10016	14,000	12	*	14,000	0	*
Sharon Crowder 29 Saddlebow Road Bell Canyon, CA 91307	234,375	16	*	234,375	0	*
Thomas W. Dana 1429 Shenandoah Pkwy Chesapeake, VA 23320	234,375	16	*	234,375	0	*
Jeffrey Davis 383 North West 112th Ave Coral Springs, FL 33071	638,750	18	*	468,750	170,000	*
Brad Dehaan 1605 Vandyk Road Lynden, WA 98264	2,343,750	26	2.0%	2,343,750	0	*
Thierry Delfosse Ave Brassine, 44 Rhode St Genese 1640 Belgium	568,750	18	*	468,750	100,000	*
Michael Doherty 14210 Stacey Street						

Greenville, MI 48838	229,687	27	*	229,687	0	*

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Richard Edwards 18506 Upper Bay Road Houston, TX 77058	2,613,750	26	2.3%	2,343,750	270,000	*
Chidi Eze 255 Livingston Street 3rd Floor Brooklyn, NY 11217	262,500	52	*	262,500	0	*
Kristina Fasullo 77 Claradon Lane Staten Island, NY 10305	150,000	12	*	150,000	0	*
Ahsan Farooqi 54 Kimberly Court S. Brunswick, NJ 08852	234,375	16	*	234,375	0	*
Frank R. Fleming 495 Washington Avenue #35 Titusville, FL 32796	46,875	29	*	46,875	0	*
Deborah Francis 28 Monsey Place Staten Island, NY 10303	13,200	12	*	13,200	0	*
William Christopher Frasco & Gina Frasco JT WROS 532 Nugent Ave Staten Island, NY 10305	165,000	12	*	165,000	0	*
Patrick Gallagher 700 N. Water Street Milwaukee, WI 53202	150,000	25	*	150,000	0	*
Michael C. Geiger 1608 Heather Heights Sykesville, MD 21784	93,750	15	*	93,750	0	*
Anthony Gentile 4280 Garibaldi Place Pleasanton, CA 94566	112,500	28	*	112,500	0	*
Gerald E. Gillett Trust UA Dated 08/18/95 Gerald E. Gillett Trustee 12 Windrush Lane Beachwood, OH 44122	75,000	30	*	75,000	0	*

Gordon & Price, Inc. Attention: John Gordon 905 W. Deyoung Street Maroin, IL 62959	140,625	19	*	140,625	0	*

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John Grant The Malthouse, Manor Lane Claverdon, Warwick CV35 8NH United Kingdom	468,750	18	*	468,750	0	*
El Hadji S Gueye 26175 Langston Avenue A Glen Oaks, NY 11004	4,000	12	*	4,000	0	*
Marshall I. Gurian 3277 East Raven Court Chandler, AZ 85249	56,250	14	*	56,250	0	*
Robert Grossman & Karen Grossman JT WROS 9515 Deerfoot Way Columbia, MD 21046	212,500	31	*	187,500	25,000	*
Steven J. Hansel & Sharon M. Hansel JT TEN 7132 Dove Court Parker, CO 80134	281,250	24	*	281,250	0	*
The Hariri Family Limited Partnership One Palmer Square, Suite 330 Princeton, NJ 08542	937,500	53	*	937,500	0	*
Christopher J. Heller 8601 Tanque Verde Road Tucson, AZ 85749	468,750	18	*	468,750	0	*
Dr. Mark T. Hellner 900 West Olive Suite A Merced, CA 95348	1,171,875	32	1.0%	1,171,875	0	*
Pershing, LLC as Custodian FBO Kenneth A. Hemstreet Rollover Account 22 W. 576 Sunset Terrace Medinah, IL 60157	468,750	18	*	468,750	0	*
Antonio Hernandez						

1578 Bengal Street El Paso, TX 79935	364,375	16	*	234,375	130,000	*
Neil Herskowitz 2109 Broadway Suite 206 New York, NY 10023	234,375	16	*	234,375	0	*
The Marianne Higgins Revocable Trust U A Dated 07/27/05 Marianne Higgins Trustee 5803 Oak Grove Street Mason Neck, VA 22079	140,625	19	*	140,625	0	*
Dave W. Hill 13240 N. Whitecloud Court Camby, IN 46113	284,375	16	*	234,375	50,000	*
Morgan Hollis & Tracey F. Hollis JT TEN 11 Bartlett Ave Nashua, NH 03064	93,750	15	*	93,750	0	*
Clifton M. Horn 125 Harrison Street Barrington, IL 60010	314,375	16	*	234,375	80,000	*
Arthur S. James Jr. 315 Magellan Drive Sarasota, FL 34243	75,000	30	*	75,000	0	*

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Ken Janckila 353 Goose Lane Carbondale, CO 81623	468,750	18	*	468,750	0	*
Christopher C. Jensen 16214 East Vista Verde Court Gilbert, AZ 85297	243,750	53	*	243,750	0	*
Robert Kantor 7 Heller Drive Upper Montclair, NJ 07043	468,750	18	*	468,750	0	*
Martin L. Karlov 55 E. Erie Street Unit 4301 Chicago, IL 60611	234,375	16	*	234,375	0	*
Brian J. Keller & Debbie M. Keller JT WROS 1246 130th Avenue New Richmond, WI 54017	328,125	33	*	328,125	0	*
Brian G. Kiernan 781 Third Avenue King of Prussa, PA 19406	468,750	18	*	468,750	0	*
Stephen N. Kitchens & Martha M. Kitchens JT WROS 1053 Lake Colonial Dr. Arrington, TN 37014	468,750	18	*	468,750	0	*
Lester Krasno 400 North 2nd Street Pottsville, PA 17901	234,375	16	*	234,375	0	*
Daniel J. Labrie & Barbara H. Labrie JT TEN P.O. Box 7116 Kensington, CT 06037	187,500	31	*	187,500	0	*
Michael J. Lane 37 Woodlands Avenue Walsall West Midlands WS5 3LN United Kingdom	448,438	34	*	398,438	50,000	*

Daniel J. Lange 131 E. Wisconsin Avenue Suite 100 Pewaukee, WI 53072	234,375	16	*	234,375	0	*

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Kenneth H. Langley 10 Lead Mine Road Leverett, MA 01054	93,750	15	*	93,750	0	*
Peter J. Lawrence 5 Landsdowne Crescent London W11 2NH United Kingdom	468,750	18	*	468,750	0	*
Ken Lehman & Karen Lehman JT WROS 5945 Grayson Road Harrisburg, PA 17111	468,750	18	*	468,750	0	*
Scott Levine 301 Avalon Pines Dr. Coram, NY 11727	20,000	12	*	20,000	0	*
George B. Lewis 1185 Porter Street A Vallejo, CA 94590	103,125	35	*	103,125	0	*
Bruce Lifrieri 15 Bryant Crescent Apt 2H White Plains, NY 10605	93,750	15	*	93,750	0	*
Barry Lind Revocable Trust U A Dated 12/19/89 Barry J. Lind Trustee 1000 West Washington St. Suite 502 Chicago, IL 60607	1,556,250	36	1.4%	1,406,250	150,000	*
Dwight E. Long 114 Addison Avenue Franklin, TN 37064	150,000	25	*	150,000	0	*
Elvin J. Lopez 59 Maiden Lane New York, NY 10038	217,125	12	*	217,125	0	*
Jim M. Macek 4356 Cloverdale Road NE Cedar Rapids, IA 52411	937,500	37	*	937,500	0	*
Anthony L. Markovic 8 Rookwood Road						

London N16 655	1,875,000	38	1.6%	1,875,000	0	*

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Michele Markowitz C/O Joseph Stevens & Co., Inc. 59 Maiden Lane 32nd Fl New York, NY 10038	400,000	12	*	400,000	0	*
Anthony Wayne McCarthy 699 Rosebank Road Avondale Auckland New Zealand	468,750	18	*	468,750	0	*
Caeron A. McClintock 59 Maiden Lane New York, NY 10038	217,125	12	*	217,125	0	*
Robert L. McEntire 112 Westcott Way Dalton, GA 30720	937,500	44	*	937,500	0	*
Jason M. McNamara 28494 Westinghouse Place #203 Valencia, CA 91355	1,921,875	41	1.7%	1,921,875	0	*
Pershing LLC as Custodian FBO Jagadish Medarametla IRA Rollover Account 7590 Wentworth Lane Mentor, OH 44060	375,000	42	*	375,000	0	*
Samuel Medina C-18 Calle S Esr San Fernando Carolina, PR 00985	240,000	43	*	240,000	0	*
Matt Meehan 114 Narrows Road South Staten Island, NY 10305	14,000	12	*	14,000	0	*
Neftali Mercedes 100 John Street, Apt 3202 New York, NY 10038	106,640	12	*	106,640	0	*
Fabio Migliaccio 658 Henry Street Brooklyn, NY 11231	354,290	12	*	354,290	0	*

Mike Milani & Lorna Milani JT TEN 2159 San Luis Road Walnut Creek, CA 94597	468,750	18	*	468,750	0	*
Amanda Miller 145 Fremont Avenue Staten Island, NY 10306	15,000	12	*	15,000	0	*
John Richard Miller 29 Bishop Kirk Place Woodstock Road N. Oxford OX2 7HJ United Kingdom	1,975,000	38	1.7%	1,875,000	100,000	*
Enrico Monaco 2230 Ocean Ave. Brooklyn, NY 11229	187,500	31	*	187,500	0	*
David R. Moore 10 Eagle Nest Cart Bolton Ontario L7W 5R8 Canada	187,500	31	*	187,500	0	*

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MSB Family Trust DTD 06/25/93 295 Shadowood Lane Northfield, IL 60093	1,062,500	44	*	937,500	125,000	*
Anthony S. Mundy 9511 Shore Road Apt 513 Brooklyn, NY 11209	134,800	12	*	134,800	0	*
Gregory Nagel & Mary Jo Nagel JT TEN 5828 Sebastian Place San Antonio, TX 78249	2,423,750	26	2.1%	2,343,750	80,000	*
David P. Nichols 2700 Oglesby Bridge Road SW Conyers, GA 30094	187,500	31	*	187,500	0	*
Oweida Orthopedic Assoc. 401K Safe Habor Plan Sam Oweida Trustee 5405 Stones Throw Court Charlotte, NC 28226	468,750	18	*	468,750	0	*
Peter Orthos 52 Stone Hill Drive S Manhasset, NY 11030	200,000	12	*	200,000	0	*
Alexandra Orthos & Peter Orthos JT WROS 52 Stone Hill Drive S Manhasset, NY 11030	1,175,920	12	1.0%	1,175,920	0	*
Jon D. Packer 59 Emerald Lane Stamford, CT 06905	937,500	44	*	937,500	0	*
Palisades Financial Ltd. 1288 Alberni Street Suite 806 Vancouver BC V6E 4N5 Canada	234,375	16	*	234,375	0	*
William C. Pawson Revocable Trust DTD 11/21/02 William C. Pawson						

Trustee 2330 North Star Lane Avon, OH 44011	2,343,750	26	2.0%	2,343,750	0	*
George Paxinos 32-43 46th Street Astoria, NY 11103	43,200	12	*	43,200	0	*
Fred Pearl & Marylou Pearl JT TEN #2 Sussex Court Rancho Mirage, CA 92270	103,125	35	*	103,125	0	*
Robert Petrozzo 20 Woods Lane East Hampton, NY 11937	617,700	12	*	617,700	0	*

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Craig T. Pio 2155 Kenwood Place Bellmore, NY 11710	703,125	45	*	703,125	0	*
Sanford Porter 833 Kehwood Avenue Daluth, MN 55811	93,750	15	*	93,750	0	*
Randall L. Powell 663A Commerce Drive Upper Marlboro, MD 20774	187,500	31	*	187,500	0	*
Vladimir Prerad 1352 Dover Court Lane Ormond Beach, FL 32174	234,375	16	*	234,375	0	*
Ronald Primuth 8312 Getting Road Racine, WI 53406	93,750	15	*	93,750	0	*
Professional Traders Fund LLC Marc Swickle and Howard Berger** 1400 Old Country Road, Suite 206 Westbury, NY 11590	366,420	46	*	366,420	0	*
Benjamin Raab Trust UAD 06/04/99 Benjamin Raab Trustee 3973 75th Street Suite 103 Aurora, IL 60504	279,375	16	*	234,375	45,000	*
David Jerome Raab 1830 Spruce Avenue Highland Park, IL 60035	234,375	16	*	234,375	0	*
Pershing LLC as Custodian F/B/O Michael J. Radlove IRA 2748 Blackbird Hollow Cincinnati, OH 45244	93,750	15	*	93,750	0	*
Charles M. Raspa 3663 Rt. 9 North, Suite 102						

Old Bridge, NY 08857	15,000	12	*	15,000	0	*
James Rathgeber 14 Richboyrne Lane Melville, NY 11747	785,700	12	*	785,700	0	*

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Stephen Renaud 6 Woodland Drive Darien, CT 06820	6,400	12	*	6,400	0	*
Peter Repole 6160 Greenbelt Road Greenbelt, MD 20770	93,750	15	*	93,750	0	*
Andrew H. Sabreen Revocable Trust D/T/D 12/17/04 Andrew H. Sabreen & Carol Sabreen Trustees 2213 Kingridge Road Pittsburgh, PA 15237	350,000	13	*	300,000	50,000	*
Donald Ronning 70 Bridge Streer #11 Pelham, NH 03076	609,375	47	*	609,375	0	*
David C. Rouse & Marcy E, Rathjen Rouse JT TEN 253 Beverly Way Gardnerville, NV 89460	93,750	15	*	93,750	0	*
Paul Sallwasser & Teri Sallwasser JT WROS 301 Windmill Palm Avenue Plantation, FL 33324	937,500	44	*	937,500	0	*
Kirt Samuel 249 B15 Street, Apt L502 Queens, NY 11691	62,000	12	*	62,000	0	*
Suzette T. Seigel 35 Watergate Drive Unit 404 Sarasota, FL 34236	234,375	16	*	234,375	0	*
Richard S. Simms II & Cynthia Simms JT WROS 5951 S. Middlefield Road Suite 105 Littleton, CO 80123	93,750	15	*	93,750	0	*
David Smith 312 Brooklea Drive						

Fayetteville, NY 13066	225,000	49	*	225,000	0	*
Patricia Sorbara 4 Windham Court Muttontown, NY 11545	400,000	12	*	400,000	0	*
Robert F. Starzel 99 22nd Avenue San Francisco, CA 94121	234,375	16	*	234,375	0	*
Michael Sternberg P.O. Box 93794 Lubbock, TX 79493	150,000	25	*	150,000	0	*

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William Strawbridge 11 Graceful Elm The Woodlands, TX 77381	150,000	25	*	150,000	0	*
Timothy Stritter 167 Ocean Blvd West Holden Beach, NC 28462	234,375	16	*	234,375	0	*
Evan S. Taub 148 Redwood Loop Staten Island, NY 10309	120,000	12	*	120,000	0	*
Scott P. Tierney P.O. Box 90333 Staten Island, NY 10309	5,000	12	*	5,000	0	*
William S. Tyrrell 2711 Edgehill Avenue Bronx, NY 10463	150,000	25	*	150,000	0	*
The Philip A. & Pricilla S. Unverzagt Living Trust U A Dated 06/24/04 Philip A. Unverzagt & Pricilla S. Unverzagt Trustees 3135 Mulberry Drive South Salem, OR 97302	937,500	44	*	937,500	0	*
Value Management Research AG Attn: Kevin Devine, CEO Campus Kronberg 7 D-61476 Kronberg im Taunus Germany	232,153	50	*	232,153	0	*
Paul Vandyke 74 Sherwood Road Norwood, NJ 07648	319,375	16	*	234,375	85,000	*
Anthony Varbero 19 Seacreast Ln. Staten Island, NY 10307	21,500	12	*	21,500	0	*
Thomas Wiles						

610 E. 9th St. Gordon, NE 69343	234,375	16	*	234,375	0	*
Dick Williams 270 Cornwall Avenue Cheshire, CT 06410	93,750	15	*	93,750	0	*
Robert Williams & Aletha Williams JT WROS 5963 North Cosby Avenue Kansas City, MO 64151	234,375	16	*	234,375	0	*
Mark A. Wilson 1930 Mount Vernon Road Southington, CT 06489	159,375	51	*	159,375	0	*
Robert Arthur Yates Abadejos 158 COI Aguilas Distrito Federal 01730 Mexico	668,750	18	*	468,750	200,000	*
Alan J. Young 1750 Braeside Avenue Northbrook, IL 60062	468,750	18	*	468,750	0	*

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* Less than 1 percent.

(1) Beneficial owner(s) based information provided to us by the selling stockholder
(2) Except as otherwise indicated, the address of each beneficial owner is c/o IR BioSciences Holdings, Inc., 4021 North 75th Street, Suite 201, Scottsdale, Arizona 85251.
(3) Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission. In general, a person who has voting power or investment power with respect to securities is treated as beneficial owner of those securities. Common shares subject to options and warrants currently exercisable or exercisable within 60 days of June 11, 2007 count as outstanding for computing the percentage beneficially owned by the person holding these options or warrants.
(4) Percentages are based on 114,322,539 shares of common stock outstanding as of June 11, 2007.
(5) Includes 1,890,930 shares of common stock underlying warrants and 5,396,970 shares of common stock underlying options that are currently exercisable or exercisable within 60 days of June 11, 2007. Includes 289,002 shares of common stock and 61,000 common stock purchase warrants held by immediate family members.
(6) Includes 80,000 shares of common stock underlying warrants that are currently exercisable or exercisable within 60 days of June 11, 2007.
(7) Includes 49,900 shares of common stock underlying warrants and 200,000 shares of common stock underlying options that are currently exercisable or exercisable within 60 days of June 11, 2007.
(8) Includes 160,000 shares of common stock underlying warrants that are currently exercisable or exercisable within 60 days of June 11, 2007. Includes 35,000 common stock purchase warrants issued by a third party that are exercisable or exercisable within 60 days of June 11, 2007.
(9) Includes 625,000 shares of common stock and 312,500 common stock purchase warrants held by The Hariri Family Limited Partnership, a partnership that our director is the administrative manager thereof, as a listed in the selling stockholder table below.
(10) Includes 2,533,541 shares of common stock underlying warrants and 5,596,970 shares of common stock underlying options that are currently exercisable or exercisable within 60 days of June 11, 2007. Includes 35,000 common stock purchase warrants issued by third parties that are exercisable or exercisable within 60 days of June 11, 2007.
(11) Includes 712,000 shares of common stock underlying warrants that are currently exercisable or exercisable within 60 days of June 11, 2007.
(12) Shares included in this registration statement are part of the total of 5,482,600 shares owned by registered representatives of Joseph Stevens & Co., Inc. and are being registered hereby per certain registration rights granted to them for participation in our private offering in December 2006.
(13) Includes 100,000 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.
(14) Includes 18,750 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.
(15) Includes 31,250 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.
(16) Includes 78,125 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.
(17) Includes 165,625 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.
(18) Includes 156,250 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.
(19) Includes 46,875 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.
(20)

Includes 68,780 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(21) Includes 546,875 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(22) Includes 118,750 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(23) Includes 265,625 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(24) Includes 93,750 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(25) Includes 50,000 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(26) Includes 781,250 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(27) Includes 76,562 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(28) Includes 37,500 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(29) Includes 15,625 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(30) Includes 25,000 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(31) Includes 62,500 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(32) Includes 390,625 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(33) Includes 109,375 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(34) Includes 132,813 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(35) Includes 34,375 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(36) Includes 468,750 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(37) Includes 312,500 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(38) Includes 625,000 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(39) Includes 150,000 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(40) Includes 162,500 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(41) Includes 640,625 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(42) Includes 125,000 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(43) Includes 80,000 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(44) Includes 312,500 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(45)

Includes 234,375 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(46) Mark Swickle and Howard Berger are the control persons of Professional Traders Fund LLC.

(47) Includes 203,125 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(48) Includes 218,750 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(49) Includes 75,000 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(50) Kevin Devine is the control person of Value Management Research AG.

(51) Includes 53,125 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(52) Includes 87,500 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

(53) Includes 312,500 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011. Our director, Robert Hariri, is the administrative manager thereof.

(54) Includes 81,250 shares underlying warrants that are currently exercisable at a price of $0.50 and expire on December 6, 2011.

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DESCRIPTION OF SECURITIES

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

We are authorized to issue 250,000,000 shares of common stock, $0.001 par value per share, of which 114,322,539 shares are issued and outstanding as of June 11, 2007.

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 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.

PREFERRED STOCK

The Company is authorized to issue 10,000,000 shares of preferred stock, par value $0.001 per share. No shares of preferred stock have been issued as of June 11, 2007.

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 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.

WARRANTS

As of June 11, 2007, there were 35,295,647 shares of common stock underlying outstanding warrants, 31,399,814 of which are currently exercisable, with exercise prices ranging from $0.01 to $2.00 per share, with a weighted average exercise price of $0.36.

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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 biotechnology 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:

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

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

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Trading in our securities could be subject to extreme price fluctuations that could adversely affect your investment. The market prices for securities of biotechnology 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 per share stock price has ranged from $0.12 to $1.00 between January 1, 2005 and June 11, 2007.

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.

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

- provide our Board of Directors with the ability to alter our bylaws without stockholder approval;
- 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;
- to 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;
- provide that vacancies on our Board of Directors may be filled by a majority of directors in office, although less than a quorum; and,
- 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.

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TRANSFER AGENT AND REGISTRAR

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 June 11, 2007, we had outstanding 114,322,539 shares of common stock.

RULE 144

Of our outstanding shares, 37,771,803 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 June 11, 2007 would equal approximately 1,143,225 shares.

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

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 the date hereof, 598,573 shares of our outstanding common stock, and 575,000 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.

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.

We are registering 598,573 shares of common stock in this registration statement pursuant to registration rights granted to the holders of these shares.

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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:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- 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;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the date of this prospectus;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise; or,
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act of 1933 as amended (the "Securities Act"), 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. The maximum commission or discount to be received by any NASD member or independent broker dealer, however, will not be greater that eight (8) percent for the sale of any securities being registered hereunder pursuant to Rule 415 of the Securities Act.

Joseph Stevens & Co., Inc., is a registered broker dealer and NASD member firm and associated persons of Joseph Stevens are listed as selling shareholders in this prospectus. Joseph Stevens & Co., Inc. served as placement agent in our private placement offering which was completed on December 6, 2006, and received, in addition to cash commissions and reimbursement of certain expenses, 5,482,600 shares of our common stock. The registration statement of which this Prospectus forms a part includes the shares of Common Stock held by associated persons of Joseph Stevens & Co., Inc. The SEC has indicated that it is their position that any broker dealer firm or associated person which is a selling shareholder is deemed an underwriter and therefore Joseph Stevens & Co., Inc. or the associated persons may be deemed an underwriter with respect to the securities being sold by it.

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The 5,482,600 shares of common stock held by Joseph Stevens & Co., Inc. and its affiliates were acquired in connection with the private placement offering which expired on December 6, 2006.

Joseph Stevens & Co., Inc. has indicated to us its willingness to act as selling agent on behalf of certain of the selling shareholders named in the Prospectus under "Selling Shareholders." that purchased our privately placed securities. All shares sold, if any, on behalf of selling shareholders by First Montauk Securities Corp would be in transactions executed by First Montauk Securities Corp on an agency basis and commissions charged to its customers in connection with each transaction shall not exceed a maximum of 4.5% of the gross proceeds. Joseph Stevens & Co, Inc. does not have an underwriting agreement with us and/or the selling shareholders and no selling shareholders are required to execute transactions through Joseph Stevens & Co. Further, other than their existing brokerage relationship as customers with Joseph Stevens & Co. no selling shareholder has any pre-arranged agreement, written or otherwise, with First Montauk Securities Corp to sell their securities through Joseph Stevens & Co.

NASD Rule 2710 requires NASD members firms (unless an exemption applies) to satisfy the filing requirements of Rule 2710 in connection with the resale, on behalf of selling shareholders, of the securities on a principal or agency basis. NASD Notice to Members 88-101 states that in the event a selling shareholder intends to sell any of the shares registered for resale in this Prospectus through a member of the NASD participating in a distribution of our securities, such member is responsible for insuring that a timely filing, if required, is first made with the Corporate Finance Department of the NASD and disclosing to the NASD the following:

- it intends to take possession of the registered securities or to facilitate the transfer of such certificates;
- the complete details of how the selling shareholders shares are and will be held, including location of the particular accounts;
- whether the member firm or any direct or indirect affiliates thereof have entered into, will facilitate or otherwise participate in any type of payment transaction with the selling shareholders, including details regarding any such transactions; and
- in the event any of the securities offered by the selling shareholders are sold, transferred, assigned or hypothecated by any selling shareholder in a transaction that directly or indirectly involves a member firm of the NASD or any affiliates thereof, that prior to or at the time of said transaction the member firm will timely file all relevant documents with respect to such transaction(s) with the Corporate Finance Department of the NASD for review.

The NASD has recently proposed rule changes to NASD Rule 2710 which may, if approved, modify the requirements of its members to make filings under NASD Rule 2710. Further, no NASD member firm may receive compensation in excess of that allowable under NASD rules, including Rule 2710, in connection with the resale of the securities by the selling shareholders, which total compensation may not exceed 8%.

We have advised the selling shareholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling shareholders and their affiliates. In addition, we will make copies of this Prospectus available to the selling shareholders for the purpose of satisfying the Prospectus delivery requirements of the Securities Act.

The shares of common stock 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., Inc. 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.

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.

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.

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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.

LEGAL MATTERS

The validity of the common stock offered by this prospectus will be passed upon for us by Kirkpatrick & Lockhart Preston Gates Ellis 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 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.

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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IR BioSciences Holdings, Inc.
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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 sheet of IR BioSciences Holdings, Inc. a development stage company as of December 31, 2006 and the related consolidated statements of losses, statement of stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2006 and the period October 22, 2002 (date of inception) through December 31, 2006. These financial statements are the responsibility of the company's management. Our responsibility is to express an opinion on the financial statements based upon our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of IR BioSciences Holdings, Inc. a development stage company at December 31, 2006 and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2006 and the period October 22, 2002 (date of inception) through December 31, 2006 in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note A to the consolidated financial statements, the Company adopted the provisions of Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment", effective January 1, 2006.

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

/s/ RUSSELL BEDFORD STEFANOU MIRCHANDANI LLP
Russell Bedford Stefanou Mirchandani LLP

New York, New York
March 23, 2007

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IR BioSciences Holdings, Inc. and Subsidiary
(A Development Stage Company)
Consolidated Balance Sheet as of December 31, 2006

Assets		
Current assets		
Cash and cash equivalents	$	2,752,103
Prepaid services and other current assets		77,899
Salary advance		1,500
Total current assets		2,831,502
Deposits and other assets		2,260
Furniture and equipment, net of accumulated depreciation of $12,242 (Note B)		28,242
Total assets	$	2,862,004
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities (Note C)		460,969
Current portion of Notes Payable (Note F)		50,000
Total current liabilities		510,969
Commitments and Contingencies (Note I)		-
Stockholders' Equity		
Preferred stock, $0.001 par value: 10,000,000 shares authorized, no shares issued and outstanding		-
Common stock, $0.001 par value; 250,000,000 shares authorized; 108,041,897 shares issued and outstanding at December 31, 2006 (Note G)		108,042
Additional paid-in capital (Notes G, H)		15,522,690
Common stock subscribed		5,483
Deficit accumulated during the development stage		(13,285,180)
Total stockholder's equity		2,351,035
Total liabilities and stockholders' equity	$	2,862,004

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
For the years ended December 31, 2006 and 2005,
And for the period of inception
(October 30, 2002) to December 31, 2006

	For the Year Ended December 31,		For the Period October 30, 2002 to December 31,
	2006	2005	2006
Revenues	$ -	$ -	$ -
Operating expenses:			
Selling, general and administrative expenses	$ 2,445,317	$ 2,534,417	$ 10,569,618
Merger fees and costs	-	-	350,000
Financing cost	-	-	90,000
Impairment of intangible asset costs	-	6,393	6,393
Total operating expenses	2,445,317	2,540,810	11,016,011
Operating loss	(2,445,317)	(2,540,810)	(11,016,011)
Other expense:			
Cost of penalty for late registration of shares	(438,601)	2,630,761	2,192,160
(Gain) loss from marking to market - warrant portion of penalty for late registration of shares	(123,505)	(254,693)	(378,198)
(Gain) loss from marketing to market - stock portion of penalty for late registration of shares	(445,673)	(314,385)	(760,058)
Interest (income) expense, net	48,508	(11,386)	1,215,265
Total other (income) expense	(959,271)	2,050,297	2,269,169
Income (loss) before income taxes	(1,486,046)	(4,591,107)	(13,285,180)
Provision for income taxes	-	-	-
Net (loss)	$ (1,486,046)	$ (4,591,107)	(13,285,180)
Net income (loss) per share - basic and diluted	$ (0.02)	$ (0.07)	$ (0.28)
Weighted average shares outstanding - basic and diluted	73,234,541	67,691,598	47,154,801

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, 2006

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Deferred Compensation	Common Stock Subscribed	Accumulated Deficit	Total
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)	-	-	-	9,250
Shares of common stock issued at $0.0006 per share to founders for services rendered in December 2002	1,405,310	1,405	(623)	-	-	-	782
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	185,578	186	30,815		-	-	31,001

December 2002							
Net loss for the period from inception (October 30, 2002) to December 31, 2002	-	-	-	-	-	(45,918)	(45,918)
Balance at December 31, 2002 (reflective of stock splits)	18,257,042	18,257	31,776	(9,000)	-	(45,918)	(4,885)

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Shares granted to consultants at $0.1392 per share for services rendered in January 2003	98,776	99	13,651	-	-	-	13,750
Sale of shares of common stock for cash at $0.1517 per share in January 2003	329,552	330	49,670	-	-	-	50,000
Shares granted to consultants at $0.1392 per share for services rendered in March 2003	154,450	154	21,346	-	-	-	21,500
Conversion of notes payable to common stock at $0.1392 per share in April 2003	1,436,736	1,437	198,563	-	-	-	200,000
Shares granted to consultants at $0.1413 per share for services rendered in April 2003	14,368	14	2,016	-	-	-	2,030
Sale of shares of common stock for cash at $0.2784 per share in May 2003	17,960	18	4,982	-	-	-	5,000
Sales of shares of common stock for cash at $0.2784 per share in June 2003	35,918	36	9,964	-	-	-	10,000
Conversion of notes payable to common stock at $0.1392 per share in June 2003	718,368	718	99,282	-	-	-	100,000
Beneficial conversion feature associated with notes issued in June 2003	-	-	60,560	-	-	-	60,560
Amortization of deferred compensation	-	-	-	9,000	-	-	9,000
Costs of GPN Merger in July 2003	2,368,130	2,368	(123,168)	-	-	-	(120,799)
Value of warrants issued with extended notes payable	-	-	189,937	-	-	-	189,937

in October 2003							
-							
Value of Company warrants issued in conjunction with fourth quarter notes payable issued October through December 2003	-	-	207,457	-	-	-	207,457
Value of warrants contributed by founders in conjunction with fourth quarter notes payable issued October through December 2003	-	-	183,543	-	-	-	183,543
Value of warrants issued for services in October through December 2003	-	-	85,861	-	-	-	85,861
Net loss for the twelve month period ended December 31, 2003	-	-	-	-	-	(1,856,702)	(1,856,702)
Balance at December 31, 2003	23,431,300	23,431	1,035,441	-	-	(1,902,620)	(843,748)

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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)	-	-	-
Shars 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	-	-	-	1,200
Shares issued at $0.50 per share to consultants for services rendered in March 2004	20,000	20	9,980	-	-	-	10,000
Shares issued to a consultant at $0.40 per share for services rendered in March 2004	2,000	2	798	-	-	-	800
Shares issued to consultants at $0.32 per share for services rendered in March 2004	91,600	92	29,220	-	-	-	29,312
Shares to be issued to consultant at $0.41 per share in April 2004 for services to be rendered through March 2005	-	-	-	(82,000)	-	-	(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	-	-	-	64,000
Conversion of Note Payable to common stock at $0.10 per share in May 2004	350,000	350	34,650	-	-	-	35,000
Beneficial Conversion Feature associated with note payable in May 2004	-	-	35,000	-	-	-	35,000
Issuance of warrants to officers and founder for services rendered in May 2004	-	-	269,208	-	-	-	269,208

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Shares to a consultant at $0.20 per share as a due diligence fee in May 2004	125,000	125	24,875	-	-	-	25,000
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	-	-	-	3,000
Issuance of warrants to note holders in April, May, and June 2004	-	-	17,915	-	-	-	17,915
Issuance of warrants to employees and consultants for services rendered in April through June 2004	-	-	8,318	-	-	-	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	-	-	-	82,000
Shares issued to a consultant in September at $0.12 to $0.22 for services rendered through September 2004	127,276	127	16,782	-	-	-	16,909
Shares issued in July to September 2004 as interest on note payable	300,000	300	35,700	-	-	-	36,000
Issuance of warrants with notes payable in July and August 2004	-	-	72,252	-	-	-	72,252
Accrued deferred compensation in August 2004 to a consultant for 100,000	-	-	-	(10,000)	-	-	(10,000)

shares at $0.10 per share, committed but unissued							
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	-	-	-	30,000
Shares issued in August 2004 at $0.16 per share to a consultant for services provided.	125,000	125	19,875	-	-	-	20,000
Shares issued in October 2004 to employees at $0.16 to $0.25 per share	48,804	49	8,335	-	-	-	8,384
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)	-	-	(23,000)

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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	-	-	-	1,363,923
Value of warrants issued with sale of common stock in October, net of costs	-	-	607,922	-	-	-	607,922
Issuance of warrant to officer in October, 2004	-	-	112,697	-	-	-	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	-	-	-	108,640
Value of warrants issued with accounts payable conversions	-	-	48,579	-	-	-	48,579
Conversion of demand loan to stock in October at $0.11 per share	93,300	93	10,170	-	-	-	10,263
Forgiveness of notes payable in October 2004	-	-	36,785	-	-	-	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	-	-	-	123,933
Value of warrants issued with officer and director conversion of liabilities	-	-	56,067	-	-	-	56,067
Conversion of debt and accrued interest to common stock at $0.075 to $0.125 per share	6,703,151						