IR BIOSCIENCES HOLDINGS INC
Form SB-2/A
July 20, 2005

AS FILED WITH THE SECURITIES AND
EXCHANGE COMMISSION ON JULY 20, 2005 REGISTRATION NO. 333-120784

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

FORM SB-2/A
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933
(AMENDMENT NO.1)

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)

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

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

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. |_|

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

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

CALCULATION OF REGISTRATION FEE

TITLE OF EACH CLASS OF SECURITIES TO BE REGISTERED	AMOUNT TO BE REGISTERED (1)	PROPOSED MAXIMUM OFFERING PRICE PER SHARE	PROPOSED MAXIMUM AGGREGATE OFFERING PRICE	AMOUNT OF REGISTRATION FEE
Common stock, $.001 par value (4)	37,141,981	$0.18(2)	$6,685,557(2)	$847(6)
Common stock, $.001 par value (5)	10,019,600	0.18(2)	1,803,528(2)	229(6)
Common stock, $.001 par value (4)	5,192,135	0.31(3)	1,609,562(3)	189
Common stock, $.001 par value (5)	5,432,891	0.31(3)	1,684,196(3)	198
Total Registration Fee	57,786,607			$387

(Footnotes to table on next page)

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

(1) In accordance with Rule 416(a), the Registrant is also registering hereunder an indeterminate number of additional shares of common stock that shall be issuable pursuant to Rule 416 to prevent dilution resulting from stock splits, stock dividends or similar transactions.

(2) Estimated pursuant to Rule 457(c) of the Securities Act of 1933 solely for

the purpose of computing the amount of the registration fee based on the average of the bid and ask prices reported on the OTC Bulletin Board on November 22, 2004.

(3) Estimated pursuant to Rule 457(c) of the Securities Act of 1933 solely for the purpose of computing the amount of the registration fee based on the average of the bid and ask prices reported on the OTC Bulletin Board on July 19, 2005.

(4) 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.

(5) 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.

(6) Previously paid.

PROSPECTUS
Subject to Completion, Dated July 20, 2005

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.

57,786,607 SHARES

IR BIOSCIENCES HOLDINGS, INC.

COMMON STOCK

This prospectus relates to 57,786,607 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 July 20, 2005, the closing sales price for our common stock on the OTCBB was $0.30 per share.

THE SECURITIES OFFERED BY THIS PROSPECTUS INVOLVE A HIGH DEGREE OF RISK. SEE "RISK FACTORS" BEGINNING ON PAGE 5.

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 July 20, 2005

TABLE OF CONTENTS

PROSPECTUS SUMMARY.....1
RISK FACTORS.....5
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS.....17
USE OF PROCEEDS.....19
DIVIDEND POLICY.....19
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.....20
BUSINESS.....30
MANAGEMENT.....44
CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.....49
PRINCIPAL AND SELLING STOCKHOLDERS.....52
DESCRIPTION OF CAPITAL STOCK.....77
SHARES ELIGIBLE FOR FUTURE SALE.....80
PLAN OF DISTRIBUTION.....81
LEGAL MATTERS.....84
EXPERTS.....84
ADDITIONAL INFORMATION.....84
INDEX TO FINANCIAL STATEMENTS.....F-1

ABOUT 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.

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, or incorporated by reference into, this prospectus. All share and per share information included in this prospectus has been adjusted for a 1-for-20 reverse split of our common stock that we effected in July 2003 and a 2-for-1 forward stock split of our common stock that we effected in April 2004.

OUR COMPANY

GENERAL

IR BioSciences Holdings, Inc. is a development-stage biopharmaceutical company. Through our wholly owned subsidiary, ImmuneRegen BioSciences, Inc., we are engaged in the research and development of health enhancing and potential life saving products. Our product development is focused around Homspera(TM), a proprietary compound that is derived from homeostatic substance P, a naturally occurring peptide. Our focus is on the research and development of products that we believe will treat the suppression of the body's immune system caused by exposure to various forms of radiation, toxic inhalants and viral infectious diseases. Currently, the majority of our efforts are in the research and development of Radilex(TM), a compound derived from Homspera, as a countermeasure to the effects of radiological and nuclear threats. Currently, we own or have obtained a license to 4 issued U.S. and foreign patents and 24 pending U.S. and foreign patent applications. As we continue our research and development efforts we will look to add to our portfolio of patents and trademarks.

COMPANY HISTORY

We were originally incorporated in Delaware in June 1985 under the name Vocaltech, Inc. to develop, design, manufacture and market products utilizing proprietary speech-generated tactile feedback devices. We completed our initial public offering of our securities in October 1987. We changed our name to InnoTek, Inc. in November 1992. In January 1992, we effected a 1-for-6.3 reverse stock split of our common stock. In December 1994, we acquired all of the outstanding stock of InnoVisions, Inc., a developer and marketer of skin protective products, discontinued our prior operations in their entirety and changed our name to DermaRx Corporation. In April 2000, we effected a reverse merger with a subsidiary of Go Public Network, Inc., which was engaged in assisting early-stage development and emerging growth companies with financial and business development services. We changed our name to GoPublicNow.com, Inc., effected a 1-for-5 reverse stock split and discontinued our prior operations in their entirety. In November 2000, we changed our name to GPN Network, Inc. In July 2001, we discontinued the operations of GPN Network, Inc. in their entirety and began looking for appropriate merger partners. Our objective became the acquisition of an operating company with the potential for growth in exchange for our securities. In July 2003, we effected a reverse merger with ImmuneRegen BioSciences, Inc. and adopted our current business model. In July 2003, we effected a 1-for-20 reverse stock split, and in April 2004, we effected a 2-for-1 stock split. ImmuneRegen BioSciences, Inc. was incorporated in October 2002; all information contained herein refers to the operations of ImmuneRegen BioSciences, Inc., our wholly-owned operational subsidiary.

RECENT DEVELOPMENTS

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

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

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

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

Further to the Private Placement, we entered into a settlement agreement with certain creditors whereby for full and complete satisfaction of claims totaling an aggregate of $158,017 (the "Claim Amount"), we issued to the creditors the following: (a) a number of shares of our common stock determined by dividing the Claim Amount by $0.125, and (b) warrants to purchase, at any time prior to the fifth anniversary following the date of issuance of the warrant, a number of shares of our common stock equal to fifty percent (50%) of the number of shares described above, at a price equal to $0.50 per share of common stock. The warrants are identical to the warrants issued in the Private Placement. Pursuant to the settlement we issued an aggregate of 1,264,138 shares of common stock and warrants to purchase 632,069 shares of common stock. Under the terms of the settlement agreement, the creditors released us from all claims, known or unknown, relating to the Claim Amount.

Between June 2003 and August 2004 eleven investors entered into fifteen convertible promissory notes totaling $558,500 with interest rates ranging between 8% and 12% and having various maturities. In October 2004, these notes were converted into equity in the aggregate amount of $558,500 plus accrued interest of $56,757. For full and complete satisfaction of debt, we issued to the note holders the following: (a) a number of shares of our common stock determined by dividing the debt amount by $0.125, and (b) warrants to purchase, at any time prior to the fifth anniversary following the date of issuance of the warrant, a number of shares of our common stock equal to fifty percent (50%) of

the number of shares described above, at a price equal to $0.50 per share of common stock. The warrants are identical to the warrants issued in the Private Placement. Pursuant to the debt conversion we issued an aggregate of 6,694,149 shares of common stock and warrants to purchase 3,347,076 shares of common stock. Under the terms of the conversion agreement, the note holders released us from all claims, known or unknown, relating to the debt amount.

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

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

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

Our board of directors appointed John N. Fermanis to serve as our Chief Financial Officer, effective as of December 22, 2004. Our Board resolved to issue 100,000 shares of registered common stock to Mr. Fermanis for his acceptance of this position. These shares were issued to Mr. Fermanis in May 2005.

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

THE OFFERING

Common stock offered by selling stockholders.....	57,786,607 shares(1)
Common stock outstanding.....	72,571,026 shares(2),(3)
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 48,934,894 shares of our common stock that were issued to selling stockholders and 8,851,713 shares of our common stock underlying warrants that were issued to selling stockholders.

(2) The number of shares of common stock outstanding as of May 31, 2005 listed above includes:

- 740,551 common shares that have been accrued due to convertible features of notes, employment and advisory agreements.

- 3,228,400 shares to be issued in connection with a penalty clause regarding the registerance of shares sold in our Private Offering in October 2004. For each 30-day period beyond 90-days following the second closing date (October 26, 2004), we have agreed to issue to the holders of units sold in the Private Offering an additional 2% a month, or in aggregate 461,200 shares and 181,600 warrants until such a time as this Registration Statement is made effective.

(3) The number of shares of common stock outstanding as of May 31, 2005 listed above excludes:

- 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.

- 150,000 10-year common stock purchase options at an exercise price of $0.40 have been granted under our 2003 Stock Option, Deferred Stock and Restricted Stock Plan; and,

- 16,342,351 shares of our common stock issuable upon exercise of warrants with exercise prices ranging from $0.05 to $2.00 per share.

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.

	FOR THE THREE MONTHS ENDED MARCH 31,		FOR THE YEAR ENDED DECEMBER 31		CUMULAT (OCT TO
	2005 (UNAUDITED)	2004 (UNAUDITED)	2004	2003	
Revenues	$ --	$ --	$ --	$ --	
Operating expenses:					
Selling, general and administrative expenses ...	838,520	931,074	4,498,390	1,045,776	
Merger fees and costs	--	--	--	350,000	
Financing cost	--	--	--	90,000	
Total operating expenses	838,520	931,074	4,498,390	1,485,776	
Operating loss	(838,520)	(931,074)	(4,498,390)	(1,485,776)	
Interest expense	977	304,078	807,017	370,926	
Total other expense	977	304,078	807,017	370,926	
Loss before income taxes ..	(839,497)	(1,235,152)	(5,305,407)	(1,856,702)	
Provision for income taxes	--	--	--	--	

Net loss	$ (839,497)	$ (1,235,152)	$ (5,305,407)	$ (1,856,702)
Net loss per share - basic and diluted	$ (0.01)	$ (0.05)	$ (0.16)	$ (0.09)
Weighted average shares outstanding - basic and diluted	62,863,440	24,845,493	33,510,168	21,317,292

ADDITIONAL INFORMATION

We were originally incorporated in Delaware under the name of Vocaltech, Inc. in June 1985. We changed our name to InnoTek, Inc. in November 1992, to DermaRx Corporation in December 1994, to GoPublicNow.com, Inc. in April 2000, to GPN Network, Inc. in November 2000 and to IR BioSciences Holdings, Inc. in August 2003. Our executive offices are located at 4021 N. 75th Street, Suite 201, Scottsdale, Arizona 85251. Our telephone number is (480) 922-3926.

In this prospectus, the terms "we," "us," 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 we are currently aware of that are facing our company. Additional risks not presently known to us may also impair our business operations. 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 AN ACCUMULATED DEFICIT, ARE NOT CURRENTLY PROFITABLE AND EXPECT TO INCUR SIGNIFICANT EXPENSES IN THE NEAR FUTURE.

We have incurred a substantial net loss for the period from our inception in October 2002 to March 31, 2005, and are currently experiencing negative cash flow. We expect to continue to experience negative cash flow and operating losses through at least 2007 and possibly thereafter. As a result, we will need

to generate significant revenues to achieve profitability.

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

We are focused on product development and have not generated any revenue to date. We have incurred operating losses since our inception. Our net loss for the three months ended March 31, 2005 and for fiscal year 2004 was $839,497 and $5,305,407, respectively. As of March 31, 2005, we had an accumulated deficit of $8,047,524.

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

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

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

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

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

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

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

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

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

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

As of March 31, 2005, our cash and cash equivalents totaled approximately $1,600,000. Based on our current plans, we believe these financial resources, and interest earned thereon, will be sufficient to meet our operating expenses and capital requirements through January 2006. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. We may require substantial additional funds in order to finance our drug discovery and development programs, fund operating expenses, pursue regulatory clearances, develop manufacturing, marketing and sales capabilities, and prosecute and defend our intellectual property rights. We may seek additional funding through public or private financing or through collaborative arrangements with strategic partners.

You should be aware that in the future:

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

If we cannot raise additional funds when needed, or on acceptable terms, we will not be able to continue to develop our drug candidates. We require substantial working capital to fund our operations. Since we do not expect to generate significant revenues in the foreseeable future, in order to fund operations, we will be completely dependent on additional debt and equity financing arrangements. There is no assurance that any financing will be sufficient to fund our capital expenditures, working capital and other cash requirements beyond January 2006. Our working capital as of March 31, 2005 was $1,198,905. No assurance can be given that any such additional funding will be available or that, if available, can be obtained on terms favorable to us. If we are unable to raise needed funds on acceptable terms, we will not be able to develop or enhance our products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, we will not be able to continue operations.

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

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

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

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

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

tested in humans. Regulatory authorities may not permit human testing of potential products based on these technologies. Even if human testing is permitted, any potential products based on Homspera may not be successfully developed or shown to be safe or effective.

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

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

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

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

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

Clinical testing, manufacture, promotion, export and sale of our proposed products are subject to extensive regulation by numerous governmental authorities in the United States, principally the FDA, and corresponding state and foreign regulatory agencies. This regulation may delay or prevent us from commercializing proposed products. Noncompliance with applicable requirements can result in, among other things, fines, injunctions, seizure or recall of such products, total or partial suspension of product manufacturing and marketing, failure of the government to grant premarket approval, withdrawal of marketing approvals and criminal prosecution.

The regulatory process for new therapeutic drug products, including the required preclinical studies and clinical testing, is lengthy and expensive. We may not receive necessary FDA clearances for any of our potential products in a timely manner, or at all. The length of the clinical trial process and the number of patients the FDA will require to be enrolled in the clinical trials in order to establish the safety and efficacy of our proposed products is uncertain.

We are currently preparing the protocols for additional formulation and stability studies. We expect these studies to be completed within 3 months. We expect to perform toxicity inhalation studies, followed by additional mouse studies. In these mouse studies we expect further validate our prior findings by collecting additional data as requested by the FDA and NIH. We expect to begin our eighth mouse study within the next 120 days. We estimate that the study will be completed within 3 months of inception at an estimated cost of $100,000. Upon completion of the aforementioned study we intend to prepare the protocols necessary for a non-human primate study to test the efficacy of Radilex as a treatment to acute radiation sickness and apply for an Investigative New Drug ("IND") application. We expect to receive an IND and begin this study within the next twelve to eighteen months.

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

The FDA has not designated expanded access protocols for Homspera as "treatment" protocols. The FDA may not determine that Homspera meets all of the FDA's criteria for use of an investigational drug for treatment use. Even if Homspera is allowed for treatment use, third party payers may not provide reimbursement for the costs

of treatment with Homspera. The FDA also may not consider Homspera to be an appropriate candidate for acceptance as Emergency Use Authorization for Promising Medical Countermeasures Under Development, accelerated approval, expedited review or fast track designation.

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

A marketed product is subject to continual FDA review. Later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market, as well as possible civil or criminal sanctions. The FDA could withdraw a previously approved product from the market upon receipt of newly discovered information, including a failure to comply with regulatory requirements, the occurrence of unanticipated problems with products following approval, or other reasons, which could adversely affect our operating results.

Among the other requirements for regulatory approval is the requirement that prospective manufacturers conform to the FDA's Good Manufacturing Practices, or GMP, requirements. In complying with the FDA's GMP requirements, manufacturers must continue to expend time, money and effort in production, record keeping and quality control to assure that products meet applicable specifications and other requirements. Failure to comply and maintain compliance with the FDA's GMP requirements subjects manufacturers to possible FDA regulatory action and as a result, may have a material adverse effect on us. We, or our contract manufacturers, if any, may not be able to maintain compliance with the FDA's GMP requirements on a continuing basis. Failure to maintain compliance could have a material adverse effect on us.

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

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

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

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

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

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

- delays in obtaining regulatory approvals to commence a study;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;

- delays in the enrollment of patients;
- lack of efficacy during clinical trials; or,
- unforeseen safety issues.

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

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

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

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

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

delay in completing clinical trials for our applications, or in receiving regulatory approval for the sale of any products resulting from our applications, may severely harm our business and reputation.

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

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

- we may not have the financial resources to continue research and development of any of our drug candidates; and,

- we may not be able to enter into collaborative arrangements relating to any drug candidate subject to delay in regulatory filing.

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

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

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

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

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

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

The manufacturing process of our proposed products is expected to involve a number of steps and requires compliance with stringent quality control specifications imposed by us and by the FDA. We have no experience in the sales, marketing and distribution of pharmaceutical or biotechnology products. We have not manufactured any of our products in commercial quantities. We may not successfully make the transition from manufacturing clinical trial quantities to commercial production quantities or be able to arrange for contract manufacturing and this could prevent us from commercializing products or limit our profitability from our products.

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

We may enter into arrangements with contract manufacturing companies in order to meet requirements for our products or to attempt to improve manufacturing efficiency. If we choose to contract for manufacturing services, we may encounter costs, delays and/or other difficulties in producing, packaging and distributing our clinical trials and finished product. Further, contract manufacturers must also operate in compliance with the GMP requirements; failure to do so could result in, among other things, the disruption of our product supplies. Our

potential dependence upon third parties for the manufacture of our proposed products may adversely affect our profit margins and our ability to develop and deliver proposed products on a timely and competitive basis.

For the manufacture of the applications under development, we obtain synthetic peptides from third party manufacturers. A synthesized version of substance P is readily available at low cost from several life science and technology companies that provide biochemical and organic chemical products and kits used in scientific and genomic research, biotechnology, pharmaceutical development and the diagnosis of disease and chemical manufacturing. If any of these proposed manufacturing operations prove inadequate, there may be no assurance that any other arrangements may be established on a timely basis or that we could establish other manufacturing capacity on a timely basis. Although, we believe that the synthetic substance P and other materials necessary to produce Homspera are readily available from various sources, and several suppliers are capable of supplying substance P in both clinical and commercial quantities, our dependence on such manufacturers, may delay or impair our ability to generate revenues, or adversely affect our profitability.

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

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

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

Our ability to market and commercialize Homspera depends on the acceptance and utilization of Homspera by the medical community. We will need to develop commercialization initiatives designed to increase awareness about us and Homspera among targeted audiences, including public health activists and community-based outreach groups in addition to the investment community. Currently, we have not developed any such initiatives. Without such acceptance of Homspera, the product upon which we expect to be substantially dependent, we may not be able to successfully commercialize Homspera or generate revenue.

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

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

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

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

injury. Companies such as VaxGen, Inc., Acambis plc and Emergent BioSolutions have developed or are developing vaccines against infectious diseases, including anthrax.

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

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

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

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

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

We own or have obtained a license to 4 issued U.S. and foreign patents and 24 pending U.S. and foreign patent applications. Our success will depend in part on our ability to obtain additional United States and foreign patent protection for our drug candidates and processes, preserve our trade secrets and operate without infringing the proprietary rights of third parties. We place considerable importance on obtaining patent protection for significant new technologies, products and processes.

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

court could revoke our patents or limit the scope of coverage for those patents.

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

infringement litigation will likely increase. On the other hand, if the USPTO or the courts begin to allow narrower claims, the value of our proprietary rights may be limited. Any changes in, or unexpected interpretations of the patent laws may adversely affect our ability to enforce our patent position.

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

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

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

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

The patent positions of biotechnology and pharmaceutical companies are often highly uncertain and involve complex legal and factual questions. Therefore, the breadth of claims allowed in biotechnology and pharmaceutical patents cannot be predicted. We also rely upon non-patented trade secrets and know how, and others may independently develop substantially equivalent trade secrets or know how. We also rely on protecting our proprietary technology in part through confidentiality agreements with our current and former corporate

collaborators, employees, consultants and certain contractors. These agreements may be breached, and we may not have adequate remedies for any such breaches. Litigation may be necessary to defend against claims of infringement, to enforce our patents or to protect trade secrets. Litigation could result in substantial costs and diversion of management efforts regardless of the results of the litigation. An adverse result in litigation could subject us to significant liabilities to third parties, require disputed rights to be licensed or require us to cease using certain technologies.

Our products could infringe on the intellectual property rights of others, which may cause us to engage in costly litigation and, if not successful, could cause us to pay substantial damages and prohibit us from selling our products. Because patent applications in the United States are not publicly disclosed until the patent application is published or the patent is issued, applications may have been filed which relate to 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 products violate third-party proprietary rights, we cannot assure you that we would be able to arrange licensing agreements or other satisfactory resolutions on commercially reasonable terms, if at all. Any claims made against us relating to the infringement of third-party propriety rights could result in the expenditure of significant financial and managerial resources and injunctions preventing us from 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 United States Patent and Trademark Office in order to determine the priority of invention. Loss of such an interference proceeding would deprive us of patent protection sought or previously obtained and could prevent us from commercializing our products. Participation in such proceedings could result in substantial costs, whether or not the eventual outcome is favorable. These additional costs could adversely affect our financial results.

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

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

operations, business and assets.

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

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

OUR COMPLIANCE WITH SECURITIES LAWS, RULES AND REGULATIONS TO WHICH WE ARE SUBJECT COULD SUBSTANTIALLY INCREASE OUR OPERATING EXPENSES AND DIVERT MANAGEMENT'S ATTENTION FROM THE OPERATION OF OUR BUSINESS.

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

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

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

RISKS RELATED TO THIS OFFERING

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

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

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

may have the effect of temporarily or permanently driving down the price of our common stock. In addition, the stock market from time to time experiences extreme price and volume fluctuations which particularly affect the market prices for emerging and life sciences companies, such as ours, and which are often unrelated to the operating performance of the affected companies. For example, our stock price has ranged from $0.09 to $1.00 between January 1, 2004 and May 23, 2005.

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

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

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

The NASD has enacted recent changes that limit quotations on the OTC Bulletin Board to securities of issuers that are current in their reports filed with the Securities and Exchange Commission. The effect on the OTC Bulletin Board of these rule changes and other proposed changes cannot be determined at this time.

The quotation of our common stock on the OTCBB does not assure that a meaningful, consistent and liquid trading market currently exists, and in recent years such market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is thus subject to this volatility.

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

Our common stock is considered to be a "penny stock" since it meets one or more of the definitions in Rules 15g-2 through 15g-6 promulgated under Section 15(g) of the Securities Exchange Act of 1934, as amended. Section 15(g) of the Securities Exchange Act of 1934, as amended, and Rule 15g-2 promulgated thereunder by the SEC require broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the

risks of penny stocks and to obtain a manually signed and dated written receipt of the document before effecting any transaction in a penny stock for the investor's account. Compliance with this and other requirements may make it more difficult for holders of our common stock to resell their shares to third parties or to otherwise dispose of them in the market or otherwise.

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

Certain of our stockholders have the right to register securities for resale that they hold pursuant to registration rights agreements. We expect to continue to incur product development and selling, general and administrative costs, and in order to satisfy our funding requirements, we will need to sell additional equity securities, which may be subject to similar registration rights. The sale or the proposed sale of substantial amounts of our common stock in the public markets may adversely affect the market price of our common stock. An aggregate of 57,786,607 shares of our common stock are being registered with the SEC in the registration statement. The registration and subsequent sales of such shares of common stock will likely have an adverse effect on the market price of our common stock.

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

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"). 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 products based on our therapies and technologies utilizing 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 our applications;

- Clinical trials may fail to demonstrate the safety and effectiveness of our applications or therapies, 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. The safe harbor for forward-looking statements under the PSLRA does not apply to our company.

USE OF PROCEEDS

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

MARKET FOR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Our common stock is approved for quotation on the NASD OTC Bulletin Board under the symbol "IRBO". Previous to July 2, 2003, the Company traded under the symbol "GPNN". 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.

	2004	
	High	Low
1st Quarter	$ 1.00	$ 0.28
2nd Quarter	0.60	0.11
3rd Quarter	0.23	0.09
4th Quarter	0.50	0.15

	2003	
	High	Low
1st Quarter	$ 0.01	$ 0.01
2nd Quarter	2.50	0.10
3rd Quarter	4.50	0.65
4th Quarter	1.13	0.28

On July 19, 2005, the closing price of our common stock as reported by the OTC Bulletin Board was $0.30 per share. There were approximately 520 shareholders of record and beneficial stockholders of our common stock as of such date. We have not paid any dividends on our common stock since inception and do not intend to do so in the foreseeable future.

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 else where in this prospectus. The analysis set forth below is provided pursuant to applicable Securities and Exchange Commission regulations and is not intended to serve as a basis for projections of future events.

Except for historical information contained herein, the matters discussed in this prospectus are forward-looking statements that are subject to certain risks and uncertainties that could cause actual results to differ materially from those set forth in such forward-looking statements. Such forward-looking statements may be identified by the use of certain forward-looking terminology, such as "may," "expect," "anticipate," "intend," "estimate," "believe," or comparable terminology that involves risks or uncertainties. Actual future results and trends may differ materially from historical and anticipated results, which may occur as a result of a variety of factors. Such risks and uncertainties include, without limitation, factors discussed in management's discussion and analysis of financial condition and results of operations set forth below, as well as in "risk factors" set forth herein. Except for our ongoing obligation to disclose material information as required by federal securities laws, we do not intend to update you concerning any future revisions to any forward-looking statements to reflect events or circumstances occurring after the date of this prospectus.

OVERVIEW

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

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

GENERAL

IR BioSciences Holdings, Inc. is a development-stage biopharmaceutical company. Through our wholly owned subsidiary, ImmuneRegen BioSciences, Inc., we are engaged in the research and development of health enhancing and potential life saving products. Our product development is focused around Homspera(TM), a proprietary compound that is derived from homeostatic substance P, a naturally occurring peptide. Our focus is on the research and development of products that we believe will treat the suppression of the body's immune system caused by exposure to various forms of radiation, toxic inhalants and viral infectious diseases. Currently, the majority of our efforts are in the research and development of Radilex(TM), a compound derived from Homspera, as a countermeasure to some of the effects caused by exposure to certain radiological and nuclear threats.

In our studies to date, we have witnessed Homspera and Radilex to have high anti-inflammatory and immunostimulatory properties. We believe the compound is well-suited for treating some of the damaging effects of radiation injury when given shortly after total body exposure to radiation. We have generated a large amount of data in rodent animal models and toxicology studies relating to the activity and safety of both Homspera and Radilex. To date we have conducted two studies and co-sponsored five mouse studies in which Radilex was administered after exposure to lethal doses of radiation. In these studies we witnessed heightened survival rates in up to 50% of the exposed mice.

We own or have obtained a license to 4 issued U.S. and foreign patents and 24 pending U.S. and foreign patent applications. As we continue our research and development efforts we will look to add to our portfolio of patents and trademarks.

PLAN OF OPERATIONS

We expect to continue to incur increasing operating losses for the foreseeable future, primarily due to our continued research and development activities attributable to new and existing products and general and administrative activities.

We spent approximately $65,849 and $21,382 for the first quarters ending March 31, 2005 and 2004, respectively, in research and development activities related to the development of Radilex as a protectant against the effects of chemical, biological, radiological and nuclear threats. 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 $281,417 in research and development activities. These costs include the manufacture and delivery of our drug by third party manufacturers, payments to Contract Research Organizations ("CRO") for consulting related to our studies and costs of performing such studies.

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

Our major research and development projects include:

DEVELOPMENT OF RADILEX AS A COUNTERMEASURE TO THE EFFECTS OF RADIOLOGICAL AND NUCLEAR THREATS.

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

We are currently preparing the protocols for additional formulation and stability studies. We expect these studies to be completed within 3 months. Following these studies, we expect to perform toxicity inhalation studies. We estimate that it will cost approximately $350,000 to complete the aforementioned studies. Following these studies we expect to begin mouse study number eight. In our eighth mouse study we expect further validate our prior studies by collecting additional data as requested by the FDA and NIH. We expect to begin the eighth study within the next 120 days. We estimate that the study will be completed within 3 months of inception at an estimated cost of $100,000. Upon completion of the aforementioned study we intend to prepare the protocols necessary for a non-human primate study to test the efficacy of Radilex as a treatment to acute radiation sickness and apply for an Investigative New Drug ("IND") application. We expect this study to begin within the next twelve to eighteen months.

If we are successful in completing the study and achieve the desired results, we will submit the necessary documentation to the FDA and other regulatory agencies for approval. We believe that Radilex can be developed and approval granted under Project BioShield, if so, we believe that the approval process will be significantly shortened and less costly. If approval for Radilex is granted in a timely manner, we expect to begin to commercialize our product immediately thereafter. We are anticipating revenues from the sale of Radilex beginning in calendar year 2007 as a treatment to the effects caused by irradiation.

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

DEVELOPMENT OF RADILEX AS A COUNTERMEASURE TO THE EFFECTS OF CHEMICAL AND BIOLOGICAL THREATS.

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

DEVELOPMENT OF HOMSPERA IN THE PROMOTION OF WOUND HEALING.

We have observed in early preclinical studies that Homspera may have an effect in promoting or accelerating wound healing. Within the next three months we plan to begin preclinical studies to determine if Homspera could become a candidate for further development as a compound used in wound healing. We believe that such an application would have a large potential market and would share synergies with potential uses for Radilex as a universal protectant. We expect to begin studies regarding the use of Homspera in the promotion of wound healing in the third quarter of calendar 2005. We do not have any research and development expenses associated with the use of Homspera in wound healing in 2004 or 2003, as our observations were generated while conducting our radiation studies. We have budgeted approximately $60,000 for the costs of such studies over the next twelve months. We anticipate the completion of such studies within eight months of commencement of the studies. If we achieve desirable results, we will design the protocols and begin studies for these indications, when capital is available. As we have only collected preliminary data and additional studies are required, we cannot predict when, if ever, a viable product can be commercialized. If we do not observe significant results or we lack the capital to further the development, we may abandon such research and development efforts; thereby limiting our future potential revenues.

We will need to generate significant revenues from product sales and or related royalties and license agreements to achieve and maintain profitability. Through March 31, 2005, we had no revenues from any product sales, royalties or licensing fees, and have not achieved profitability on a quarterly or annual

basis. Our ability to achieve profitability depends upon, among other things, our ability to develop products, obtain regulatory approval for products under development and enter into agreements for product development, manufacturing and commercialization. Moreover, we may never achieve significant revenues or profitable operations from the sale of any of our products or technologies.

OFF-BALANCE SHEET ARRANGEMENTS

There were no off-balance sheet arrangements made in the fiscal quarter ended March 31, 2005.

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

REVENUES

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

COSTS AND EXPENSES

From our inception through March 31, 2005, we have incurred losses of $8,047,524. These expenses were associated principally with equity-based compensation to employees and consultants, product development costs and professional services.

LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2005, we had current assets of $1,607,085 consisting of cash of $1,600,000 and other current assets of $7,085. At March 31, 2005, we also had current liabilities of $408,180, consisting of accounts payable and accrued liabilities of $341,210 and notes payable of $66,970. This resulted in net working capital at March 31, 2005 of $1,198,905. During the three months ended March 31, 2005, the Company used cash in operating activities of ($550,971). From the date of inception (October 30, 2002) to March 31, 2005, the Company has had a net loss of ($8,047,524) and has used cash of ($2,625,316) in operating activities.

The Company currently has 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, the Company has financed its 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, 2005 via the private placement of $3,259,903 of our common stock, including $1,190,857 net of costs from the exercise of common stock purchase warrants and $973,500 from the issuance of notes payable, net of repayments.

In January 2005, we made a tender offer to temporarily reduce the exercise

price of certain warrants issued in October 2004 from $0.50 to $0.20 per share. The tender offer expired on March 4, 2005. We accepted for exercise a total of 6,600,778 warrants validly tendered and not withdrawn pursuant to the terms of the tender offer, which represents approximately 48% of the aggregate 13,780,449 warrants that were subject to the offer. We raised an aggregate of $1,190,857 from the tender offer, net of costs.

During the three months ended March 31, 2005, the Company paid a note payable in the amount of $10,000.

At March 31, 2005, the Company had outstanding two unsecured notes payable to Company shareholders in the aggregate amount of $66,970. Interest accrues at 8% per annum. Accrued interest at March 31, 2005 is $8,946. These notes were in default at March 31, 2005. One of the two notes payable as of March 31, 2005 was subsequently repaid in full for $4,998 ($3,900 principal & $1,098 accrued interest) on April 11, 2005, releasing the Company from further obligations under the note. On June 7, 2005, the remaining note in the principal amount of $50,000 and all accrued interest of $15,003 were converted into 232,153 shares of our common stock in accordance with the terms of the note.

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

Between June 2003 and August 2004 eleven investors entered into fifteen convertible promissory notes totaling $558,500 with interest rates ranging between 8% and 12% and having various maturities. In October 2004, these notes were converted into equity in the aggregate amount of $558,500 plus accrued interest of $56,757. For full and complete satisfaction of debt, we issued to the note holders the following: (a) a number of shares of our common stock determined by dividing the debt amount by $0.125, and (b) warrants to purchase, at any time prior to the fifth anniversary following the date of issuance of the warrant, a number of shares of our common stock equal to fifty percent (50%) of the number of shares described above, at a price equal to $0.50 per share of common stock. The warrants are identical to the warrants issued in the Private Placement. Pursuant to the debt conversion we issued an aggregate of 6,694,149 shares of common stock and warrants to purchase 3,347,076 shares of common stock. Under the terms of the conversion agreement, the note holders released us from all claims, known or unknown, relating to the debt amount.

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

Pursuant to our employment agreement with John Fermanis, our Chief Financial Officer, dated February 15, 2005, we paid a salary of $60,000 until the company completed a financing of $500,000 or more. This occurred on March 4, 2005 when the company completed a Tender Offer for warrants totaling $1,190,857 net of fees. From March 4, 2005, until December 31, 2005, we will pay an annual salary of $85,000. Thereafter, we will pay an annual salary of $98,000 for the

second year ending December 31, 2006 and an annual salary of $112,000 for the third year ending December 31, 2007. Mr. Fermanis' salary is payable in regular installments in accordance with the customary payroll practices of our company.

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

Since our inception, we have been seeking additional third-party funding. During such time, we have retained a number of different investment banking firms to assist us in locating available funding; however, we have not yet been successful in obtaining any of the long-term funding needed to make us into a commercially viable entity. During the period from October 2004 to March 2005, we were able to obtain financing of $3,590,136 from a series of private placements of our securities (which resulted in net proceeds to us of $3,182,845). Based on our current plan of operations all of our current funding is expected to be depleted by the end of January 2006. If we are not successful in generating sufficient liquidity from operations or in raising sufficient capital resources, it would have a material adverse effect on our business, results of operations, liquidity and financial condition.

While we have successfully raised capital to meet our working capital and financing needs in the past through debt and equity financings, additional financing will be required in order to implement our business plan and to meet our current and projected cash flow deficits from operations and development. There can be no assurance that we will be able to consummate future debt or equity financings in a timely manner on a basis favorable to us, or at all. If we are unable to raise needed funds, we will not be able to develop or enhance our products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets or seeking an acquisition partner.

Until such time, if at all, as we receive adequate funding, we intend to continue to defer payment of all of our obligations which are capable of being deferred, which actions have resulted in some vendors demanding cash

payment for their goods and services in advance, and other vendors refusing to continue to do business with us. In the event that we are successful in obtaining third-party funding, we do not expect to generate a positive cash flow from our operations for at least several years, if at all, due to anticipated expenditures for research and development activities, administrative and marketing activities, and working capital requirements and expect to continue to attempt to raise further capital through one or more further private placements. Based on our operating expenses and anticipated research and development activities, we believe that we will require an additional $1 million to meet our expenses over the next 12 months.

ACQUISITION OR DISPOSITION OF PLANT AND EQUIPMENT

We did not dispose or acquire any significant property, plant or equipment during the first quarter ended March 31, 2005.

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

NUMBER OF EMPLOYEES

From our inception through the period ended March 31, 2005, we have relied on the services of outside consultants for services and currently have five total employees, two contract employees and three full-time employees. Our full-time employees are Michael K. Wilhelm, our Chief Executive Officer; John Fermanis, our Chief Financial Officer; and, the third serves in an administrative role. In order for us to attract and retain quality personnel, we anticipate we will have to offer competitive salaries to future employees. We do not anticipate our employment base will significantly change during the next twelve months, other than the addition of one senior level appointment to the position of Senior Vice President of Scientific Development. As we continue to expand, we will incur additional cost for personnel. This projected increase in personnel is dependent upon our generating revenues and obtaining sources of financing. There is no guarantee that we will be successful in raising the funds required or generating revenues sufficient to fund the projected increase in the number of employees.

CRITICAL ACCOUNTING POLICY

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

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

STOCK-BASED COMPENSATION

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

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

our

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

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

RECENT ACCOUNTING PRONOUNCEMENTS

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

In December 2004, the FASB issued SFAS No.152, "Accounting for Real Estate Time-Sharing Transactions--an amendment of FASB Statements No. 66 and 67" ("SFAS 152) The amendments made by Statement 152 This Statement amends FASB Statement No. 66, Accounting for Sales of Real Estate, to reference the financial accounting and reporting guidance for real estate time-sharing transactions that is provided in AICPA Statement of Position (SOP) 04-2, Accounting for Real Estate Time-Sharing Transactions. This

Statement also amends FASB Statement No. 67, Accounting for Costs and Initial Rental Operations of Real Estate Projects, to state that the guidance for (a) incidental operations and (b) costs incurred to sell real estate projects does not apply to real estate time-sharing transactions. The accounting for those

operations and costs is subject to the guidance in SOP 04-2. This Statement is effective for financial statements for fiscal years beginning after June 15, 2005. with earlier application encouraged. The Company does not anticipate that the implementation of this standard will have a material impact on its financial position, results of operations or cash flows.

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

On December 16, 2004, FASB issued Statement of Financial Accounting Standards No. 153, Exchanges of Nonmonetary Assets, an amendment of APB Opinion No. 29, Accounting for Nonmonetary Transactions ("SFAS 153"). This statement amends APB Opinion 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. Under SFAS 153, if a nonmonetary exchange of similar productive assets meets a commercial-substance criterion and fair value is determinable, the transaction must be accounted for at fair value resulting in recognition of any gain or loss. SFAS 153 is effective for nonmonetary transactions in fiscal periods that begin after June 15, 2005. The Company does not anticipate that the implementation of this standard will have a material impact on its financial position, results of operations or cash flows.

RESULTS OF OPERATIONS FOR THE THREE MONTH PERIOD ENDED MARCH 31, 2005 AND FOR THE PERIOD OF INCEPTION (OCTOBER 30, 2002) TO MARCH 31, 2005.

REVENUE

We are in the development stage and have no revenue.

SALES, GENERAL, AND ADMINISTRATIVE EXPENSES

Sales, general, and administrative expenses ("SG&A") were $838,520 for the three months ended March 31, 2005, a decrease of $92,554 or approximately 10% compared to SG&A of $931,074 during the three months ended March 31, 2004. For the three months ended March 31, 2005, this amount consisted primarily of non-cash compensation issued to consultants of $299,943, legal and accounting fees of $161,806, other consulting fees of $117,739, payroll and related costs of $77,574, and research and development expenses of $65,849.

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

INTEREST EXPENSE

Interest expense was $977 for the three months ended March 31, 2005, a decrease of $303,101 or approximately 99% compared to interest expense of $304,078 for the three months ended March 31, 2004. Interest expense was dramatically reduced because the Company paid or converted to equity most of its outstanding debt during the three months ended December 31, 2004.

The Company expects interest expense to remain at low levels during the coming twelve months.

NET LOSS

For the reasons above, the net loss for the three months ended March 31, 2005 was $839,497, a decrease of $395,655 or 32% compared to a net loss of $1,235,152 for the three months ended March 31, 2004.

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

SALES, GENERAL, AND ADMINISTRATIVE EXPENSES

Sales, general, and administrative expenses ("SG&A") were $6,428,404 from the period of inception (October 30, 2002) to March 31, 2005.

INTEREST EXPENSE

Interest expense was $1,179,120 from the period of inception (October 30, 2002) to March 31, 2005.

NET LOSS

Our net loss was $8,047,524 from the period of inception (October 30, 2002) to March 31, 2005.

RESULTS OF OPERATIONS FOR THE TWELVE MONTH PERIOD ENDED DECEMBER 31, 2004 COMPARED TO THE TWELVE MONTH PERIOD ENDED DECEMBER 31, 2003.

REVENUE

We are in the development stage and have no revenue.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

Selling, general and administrative expenses were $4,498,390 for the twelve months ended December 31, 2004 which is an increase of $3,452,614 or 330% compared to selling, general and administrative expenses of $1,045,776 for the twelve months ended December 31, 2003. These expenses are primarily comprised of non-cash compensation of $3,284,577, legal and accounting fees of $271,077, officer wages of $175,000, research and development costs of $150,091, consulting fees of $169,311, and contract labor of $89,989.

Over the coming twelve months, we expect legal and accounting fees to remain high due to the compliance requirements of our company's publicly-traded status. In addition, we intend to investigate possible acquisitions and strategic alliance arrangements which will require legal and accounting due diligence. Expenses related to contract labor and personnel are expected to increase over the coming twelve months as our overhead and adm