IR BIOSCIENCES HOLDINGS INC
Form SB-2/A
April 07, 2006

AS FILED WITH THE SECURITIES AND
EXCHANGE COMMISSION ON APRIL 7, 2006 REGISTRATION NO. 333-120784

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

FORM SB-2/A
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933
(AMENDMENT NO. 4)

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

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

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

MICHAEL K. WILHELM, CHIEF EXECUTIVE OFFICER
4021 NORTH 75TH STREET, SUITE 201
SCOTTSDALE, ARIZONA 85251
(480) 922-3926
(NAME, ADDRESS AND TELEPHONE NUMBER OF AGENT FOR SERVICE)

COPIES TO
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ANH Q. TRAN, ESQ.
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LOS ANGELES, CA 90067
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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 | PRO AGGR |
|---|---|---|---|
| Common stock, $.001 par value (7) | 33,075,843 | $ 0.18(2) | $ 5, |
| Common stock, $.001 par value (8) | 10,019,600 | 0.18(2) | 1, |
| Common stock, $.001 par value (7) | 5,192,135 | 0.31(3) | 1, |
| Common stock, $.001 par value (8) | 5,432,891 | 0.31(3) | 1, |
| Common stock, $.001 par value (7) | 2,545,140 | 0.50(4) | 1, |
| Common stock, $.001 par value (7) | 1,928,400 | 0.23(5) | |
| Common stock, $.001 par value (7) | 5,708,938 | 0.32(6) | 1, |
| Common stock, $.001 par value (8) | 642,800 | 0.32(6) | |
| Total Registration Fee | ========= | | |

(Footnotes to table on next page)

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

(2) Estimated pursuant to Rule 457(c) of the Securities Act of 1933 solely for the purpose of computing the amount of the registration fee based on the average of the bid and ask prices reported on the OTC Bulletin Board on November 22, 2004.

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

(4) Estimated pursuant to Rule 457(c) of the Securities Act of 1933 solely for the purpose of computing the amount of the registration fee based on the average of the bid and ask prices reported on the OTC Bulletin Board on November 11, 2005.

(5) Estimated pursuant to Rule 457(c) of the Securities Act of 1933 solely for the purpose of computing the amount of the registration fee based on the average of the bid and ask prices reported on the OTC Bulletin Board on February 16, 2006.

(6) 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 April 4, 2006.

(7) 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.

(8) 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.

(9) Previously paid.

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.

PROSPECTUS
Subject to Completion, Dated April 7, 2006

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.

64,545,747 SHARES

IR BIOSCIENCES HOLDINGS, INC.

COMMON STOCK

This prospectus relates to 64,545,747 shares of common stock of IR BioSciences Holdings, Inc. that may be sold from time to time by the selling stockholders named in this prospectus. We will not receive any proceeds from the sales by the selling stockholders, but we will receive funds from the exercise of warrants held by selling stockholders, if exercised.

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Our common stock is traded on the OTC Bulletin Board maintained by the

National Association of Securities Dealers, Inc. under the symbol "IRBO." On April 4, 2006, the closing sales price for our common stock on the OTC Bulletin Board was $0.30 per share.

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

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

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The date of this prospectus is _____ ___, 2006

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## PROSPECTUS SUMMARY

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

## OUR COMPANY

### GENERAL

IR BioSciences Holdings, Inc. is a development-stage biopharmaceutical company. Through our wholly owned subsidiary, ImmuneRegen BioSciences, Inc., we are engaged in the research and development of potential therapeutics for a number of applications. All therapeutics in development are based on Sar9, Met (O2)11-Substance P, an analog of the naturally occurring human neuropeptide Substance P. This neuropeptide can be found throughout the body, including in the airways of humans and many other species. We use the generic name Homspera to refer to the synthetic Sar9, Met (O2)11-Substance P peptide. All of our research and development efforts are early, pre-clinical stage and Homspera has only undergone exploratory studies to evaluate its biological activity in small animals.

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

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

We have filed patent applications and provisional patent applications, where applicable, in many jurisdictions, inside and outside of the United States, for the use of the active ingredient Sar9, Met (O2)11-Substance P in

applications that we are researching. We own two issued U.S. and two issued foreign patents and two pending Patent Cooperation Treaty (PCT) applications, seven pending U.S. provisional patent applications and 16 pending foreign provisional patent applications.

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



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

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

COMPANY HISTORY

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

we effected a 1-for-20 reverse stock split, and in April 2004, we effected a 2-for-1 stock split. ImmuneRegen BioSciences, Inc. was incorporated in October 2002; all information contained herein refers to the operations of ImmuneRegen BioSciences, Inc., our wholly-owned operational subsidiary.

RECENT DEVELOPMENTS

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

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

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

In January 2005, we made a tender offer to temporarily reduce the exercise price of certain warrants issued in October 2004 from $0.50 to $0.20 per share. The tender offer expired on March 4, 2005. We accepted for exercise a



total of 6,600,778 warrants validly tendered and not withdrawn pursuant to the terms of the tender offer, which represents approximately 48% of the aggregate 13,780,449 warrants that were subject to the offer.

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

In October 2004, we completed a private placement, whereby we sold an aggregate of $2,450,000 worth of units to accredited investors. Each unit was sold for $10,000 and consisted of (a) a number of shares of our common stock determined by dividing the unit price by $0.125, and (b) a warrant to purchase, at any time prior to the fifth anniversary following the date of issuance of the warrant, a number of shares of our common stock equal to fifty percent (50%) of the number of shares included within the unit, at a price equal to $0.50 per share of common stock. We issued in the private placement an aggregate of 19,600,000 shares of our common stock and warrants to purchase 9,800,000 shares of our common stock. In consideration of the investment, we granted to each investor certain registration rights and anti-dilution rights. We agreed to register these shares along with the shares underlying these warrants within ninety days from the closing date of the transaction, or we would incur a penalty equivalent to an additional 2% of the shares and warrants to be registered for every 30 days that we fail to complete this registration. This penalty amounts to an aggregate of 461,200 shares and 181,600 warrants per 30 day period until such a time as a registration statement that includes these shares and warrants is made effective. At March 31, 2006, we have accrued liabilities to issue 6,625,907 shares of common stock and warrants to purchase an additional 2,608,987 shares for total shares of 9,234,895. The original values of these liabilities were $2,448,511 for the shares, and $744,177 for the warrants for a total of $3,188,691. Additions for the quarter ended March 31, 2006 were 1,383,600 shares of common stock with a market value of approximately

$456,588 and warrants to purchase 544,800 shares of common stock with a value of approximately $105,339.

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

Further to the private placement, we entered into a settlement agreement with certain creditors whereby for full and complete satisfaction of claims totaling an aggregate of $157,218, we issued to the creditors the following: (a) a number of shares of our common stock determined by dividing the $157,218 by $0.125, and (b) warrants to purchase, at any time prior to the fifth anniversary following the date of issuance of the warrant, a number of shares of our common stock equal to fifty percent (50%) of the number of shares described above, at a price equal to $0.50 per share of common stock. The warrants are identical to the warrants issued in the private placement. Pursuant to the settlement we issued an aggregate of 1,257,746 shares of common stock and warrants to purchase 628,873 shares of common stock. Under the terms of the settlement agreement, the creditors released us from all claims, known or unknown, relating to the $157,218 claim amount.

Between June 2003 and August 2004 eleven investors entered into fifteen convertible promissory notes totaling $558,500 with interest rates ranging between 8% and 12% and having various maturities. In October 2004, these notes were converted into equity in the aggregate amount of $558,500 plus accrued interest of $56,757. For full and complete satisfaction of debt, we issued to the note holders the following: (a) a number of shares of our common stock determined by dividing the debt amount by an amount between $0.075 and $0.125, and (b) warrants to purchase, at any time prior to the fifth anniversary following the date of issuance of the warrant, a number of shares of our common stock equal to fifty percent (50%) of the number of shares described above, at a price equal to $0.50 per share of common stock. The warrants are identical to the warrants issued in the October 2004 private placement. Pursuant to the debt conversion we issued an aggregate of 6,694,149 shares of common stock and



warrants to purchase 3,347,076 shares of common stock. Under the terms of the conversion agreement, the note holders released us from all claims, known or unknown, relating to the debt amount.

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

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

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

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

THE OFFERING

| | |
|---|---|
| Common stock offered by selling stockholders | 64,545,747 shares(1) |
| Common stock outstanding | 69,536,322 shares(2) |
| Use of proceeds | We will not receive any proceeds from the sale of the common stock, but we will receive funds from the exercise of warrants by selling stockholders, if exercised. |
| OTC Bulletin Board | IRBO |

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(1) Represents 54,351,234 shares of our common stock that were issued to selling stockholders and 10,194,513 shares of our common stock underlying warrants that were issued to selling stockholders.

(2) The number of shares of common stock outstanding as of April 4, 2006 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 shares of common stock issuable upon the exercise of five-year purchase options at an exercise price of $0.44 granted under our 2003 Stock Option, Deferred Stock and Restricted Stock Plan;
- 103,030 shares of common stock issuable upon the exercise of five-year purchase options at an exercise price of $0.33 granted under our 2003 Stock Option, Deferred Stock and Restricted Stock Plan;
- 1,000 shares of common stock issuable upon the exercise of five-year purchase options at an exercise price of $0.31 granted under our 2003 Stock Option, Deferred Stock and Restricted Stock Plan;
- 11,616,869 shares of our common stock issuable upon exercise of warrants with exercise prices ranging from $0.01 to $2.00 per share; and
- 183,530 shares of common stock that have been approved for issuance by our Board of Directors that are not yet issued.

The total number of shares of common stock offered for resale by the selling stockholders listed in this prospectus includes 6,456,800 shares of issued and outstanding common stock and 2,542,400 shares of common stock issuable upon the exercise of five-year warrants with an exercise price of $0.50



issued in connection with a penalty clause regarding the registration of shares sold in our private placement in October 2004. For each 30-day period beyond 90-days following the second closing date (October 26, 2004), we have agreed to

issue to the holders of units sold in the private placement an additional 2% a month, or in aggregate 461,200 shares and 181,600 warrants until such a time as this Registration Statement is declared effective by the Securities and Exchange Commission. We have committed these shares although they remain unissued.

SUMMARY FINANCIAL INFORMATION

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

| | For the Year Ended December 31, 2005 | For the Year Ended December 31, 2004 | For the Octobe 2002 (Inc to Decem 200 |
|---|---|---|---|
| Operating expenses: | | | |
| Selling, general and administrative expenses | $ 2,534,417 | $ 4,498,390 | $ 8,12 |
| Merger fees and costs | -- | -- | 35 |
| Financing cost | -- | -- | 9 |
| Impairment of intangible asset | 6,393 | -- | |
| Total operating expenses | 2,540,810 | 4,498,390 | 8,57 |
| Operating loss | (2,540,810) | (4,498,390) | (8,57 |
| Other expense: | | | |
| Cost of penalty for late registration of shares | 2,630,761 | -- | 2,63 |
| Gain from marking to market - warrant portion of penalty for late registration of shares | (254,693) | -- | (25 |
| Gain from marking to market - stock portion of penalty for late registration of shares | (314,385) | -- | (31 |
| Interest (income) expense, net | (11,386) | 807,017 | 1,16 |
| Total other (income) expense | (2,050,297) | 807,017 | 3,22 |
| Loss before income taxes | (4,591,107) | (5,305,407) | (11,79 |
| Provision for income taxes | -- | -- | |
| Net loss | $ (4,591,107) | $ (5,305,407) | $(11,79 |
| Net loss per share - basic and diluted | $ (0.07) | $ (0.16) | $ |
| Weighted average shares outstanding - basic and diluted | 67,691,598 | 33,510,168 | 38,93 |

ADDITIONAL INFORMATION

We are incorporated in State of Delaware. Our executive offices are

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

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



## RISK FACTORS

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

### RISKS RELATED TO OUR FINANCIAL RESULTS

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

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

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

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

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

Our independent certified public accountants have stated in their report included in this Form 10-KSB/A that the Company has incurred a net loss and negative cash flows from operations of $4,591,107 and $1,884,113, respectively,

for the year ended December 31, 2005, and a lack of operational history, among other matters, that raise substantial doubt about its ability to continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business. The effect of this going concern would materially and adversely affect our ability to raise capital, our relationship with potential suppliers and customers, and have other unforeseen effects.

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

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

You should be aware that in the future:

- 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 April 2006. Our working capital deficit as of December 31, 2005 was $211,761 net of the accrual of securities pursuant to the penalty provision of our October 2004 private placement. No assurance can be given that any such additional funding will be available or that, if available, can be obtained on terms favorable to us. If we are unable to raise needed funds on acceptable terms, we will not be able to develop or enhance our products, take advantage of any future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, we will not be able to continue operations.

WE HAVE DEFERRED, AND MAY CONTINUE TO DEFER, PAYMENT OF SOME OF OUR OBLIGATIONS, WHICH MAY ADVERSELY AFFECT OUR ABILITY TO OBTAIN GOODS AND SERVICES IN THE FUTURE.

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

us, which may adversely affect our ability to obtain goods and services in the future, or to do so on favorable terms.

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

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

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

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

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

## RISKS RELATED TO OUR BUSINESS

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



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

- ensure that any potential drug candidate would function as intended in large animal studies or human clinical applications;
- obtain the regulatory approvals necessary to commercialize products

that we may develop in the future;

- manufacture, or arrange for third-parties to manufacture, future products in a manner that will enable us to be profitable;

- establish many of the business functions necessary to operate, including sales, marketing, administrative and financial functions, and establish appropriate financial controls;

- make, use, and sell future products without infringing upon third party intellectual property rights; or

- respond effectively to competitive pressures.

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

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

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

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

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

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

Our failure to develop and commercialize products successfully will cause us to cease operations. Our current potential drug candidates, Radilex and Viprovex, will require significant additional research and development efforts and regulatory approvals prior to potential commercialization in the future. We

cannot guarantee that we will ever obtain any regulatory approvals of Homspera, Radilex or Viprovex. We currently are focusing our core competencies on the development of Radilex and Viprovex although there may be no assurance that we



will be successful in so doing.

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

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

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

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

We do not believe any drug has ever been approved and commercialized for the treatment of severe acute radiation injury. In addition, the incidence of large-scale exposure to nuclear, radiological or biological agents has been low. Accordingly, even if Radilex, our current drug candidate to treat aspects of acute radiation syndrome (ARS) and Viprovex, our drug candidate to treat exposure to various biological agents, are approved by the FDA, we cannot predict with any certainty the size of the markets for them, if any. The potential market for Radilex and Viprovex is largely dependent on the size of stockpiling orders, if any, procured by the U.S. and foreign governments. While a number of governments have historically stockpiled drugs to treat indications such as smallpox, anthrax exposure, plague, tularemia and certain long-term effects of radiation exposure, we are unaware of any significant stockpiling orders for drugs to treat ARS.

To date, although we have filed formal responses to governmental grants, Request for Information (RFI) and Request for Proposal (RFP) for

therapeutics to treat ARS and exposure to various chemical and biological agents, none have resulted in funding, stockpiling orders or a commitment to purchase our potential products, if any. Additionally, we cannot guarantee that our response to any future RFI, RFP or other grant application will result in funding, stockpiling orders or a commitment to purchase our potential products, if any.

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

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

The process of obtaining FDA and other regulatory approvals is time



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

- 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;

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

- o suspending manufacturing; or,

- o withdrawing marketing clearance.

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

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

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

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



WOULD ADVERSELY AFFECT OUR LEVELS OF FUTURE REVENUES, IF ANY.

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

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

CLINICAL TRIALS MAY FAIL TO DEMONSTRATE THE SAFETY AND EFFICACY OF OUR POTENTIAL DRUG CANDIDATES, THE EFFECT OF WHICH COULD PREVENT OR SIGNIFICANTLY DELAY

REGULATORY APPROVAL AND THEREFORE ADVERSELY AFFECT THE TIMING AND LEVEL OF FUTURE REVENUES, IF ANY.

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

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

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

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.

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

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

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

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

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

We may enter into arrangements with contract manufacturing companies in order to meet requirements for Radilex, Viprovex and Homspera or to attempt to improve manufacturing efficiency. If we choose to contract for manufacturing services, we may encounter costs, delays and/or other difficulties in producing, packaging and distributing our clinical trials and finished product, if any. Further, contract manufacturers must also operate in compliance with the cGMP requirements; failure to do so could result in, among other things, the disruption of our proposed product supplies. Our planned dependence upon third parties for the manufacture of our proposed products may adversely affect our potential profit margins, if any, and our ability to develop and deliver proposed products on a timely and competitive basis.

For the manufacture of Radilex, Viprovex and Homspera, we obtain synthetic peptides from third party manufacturers. If any of these proposed

manufacturing operations prove inadequate, there may be no assurance that any other arrangements may be established on a timely basis or that we could establish other manufacturing capacity on a timely basis. Although, we believe that the synthetic substance P and other materials necessary to produce Radilex, Viprovex and Homspera are readily available from various sources, and several suppliers are capable of supplying Homspera in both clinical and commercial quantities, our dependence on such manufacturers, may delay or impair our ability to generate revenues, or adversely affect our profitability.

ADVERSE DETERMINATIONS CONCERNING PRODUCT PRICING, REIMBURSEMENT AND RELATED MATTERS COULD PREVENT US FROM SUCCESSFULLY COMMERCIALIZING RADILEX, VIPROVEX AND HOMSPERA WHICH WOULD ADVERSELY AFFECT OUR LEVEL OF FUTURE REVENUES, IF ANY.

Our ability to earn any revenue on Radilex, Viprovex or any other



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

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

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

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

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

financial performance.

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

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

Our long-term success largely depends on our ability to market technologically competitive processes and products. If we fail to obtain or maintain these protections, we may not be able to prevent third parties from using our proprietary rights. Our currently pending or future patent applications may not result in issued patents. In the United States, patent applications are confidential until patent applications are published or the 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, WHICH WOULD ADVERSELY AFFECT OUR LEVEL OF FUTURE REVENUES, IF ANY.

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

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

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

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

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

In addition, if another party claims the same subject matter or subject



matter overlapping with the subject matter that we have claimed in a United States patent application or patent, we may decide or be required to participate in interference proceedings in the USPTO in order to determine the priority of invention. Loss of such an interference proceeding would deprive us of patent protection sought or previously obtained and could prevent us from

commercializing our potential products. Participation in such proceedings could result in substantial costs, whether or not the eventual outcome is favorable. These additional costs could adversely affect our financial results.

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

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

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

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

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

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

## RISKS RELATED TO THIS OFFERING

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

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

difficult to obtain and holders of common stock may be unable to resell their securities at or near their original offering price or at any price.

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

The quotation of our common stock on the OTCBB does not assure that a meaningful, consistent and liquid trading market currently exists, and in recent



years such market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is thus subject to this volatility.

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

Certain of our stockholders have the right to register securities for resale that they hold pursuant to registration rights agreements. We expect to continue to incur product development and selling, general and administrative costs, and in order to satisfy our funding requirements, we will need to sell additional equity securities, which may be subject to similar registration rights. The sale or the proposed sale of substantial amounts of our common stock in the public markets may adversely affect the market price of our common stock. An aggregate of 64,545,747 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.

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

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

Under the October 2004 private placement, we agreed to register the shares sold in the transaction, along with the shares underlying the warrants sold within ninety days from the closing date of the private placement. If these securities were not so registered, we would incur a penalty equivalent to an additional 2% of the shares and warrants to be registered for every 30 days that we failed to complete the registration. Through March 31, 2006, we have accrued 6,625,987 shares and 2,608,987 warrants pursuant to this penalty provision. No cap exists to limit the penalty for failure to register the shares and warrants in the October 2004 private placement. Accordingly, the amount of additional



equity securities we issue pursuant to the delayed registration penalty may adversely affect the market price of our common stock and the rights of our stockholders may be substantially reduced. Moreover, our authorized capital consists of 100,000,000 shares of common stock. As of March 31, 2006, we have fully diluted 90,633,160 shares of common stock outstanding. Therefore, because no cap exists to limit the issuance of penalty shares, we may not have a sufficient number of authorized shares available for the settlement of the registration penalty. As a result, the investors entitled to these shares may take legal or other action against us, which may cause us to pay substantial damages and adversely affect our business.

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

Our common stock is considered to be a "penny stock" since it does not qualify for one of the exemptions from the definition of "penny stock" under Section 3a51-1 of the Securities Exchange Act for 1934 as amended (the "Exchange Act"). Our common stock is a "penny stock" because it meets one or more of the following conditions (i) the stock trades at a price less than $5.00 per share; (ii) it is NOT traded on a "recognized" national exchange; (iii) it is NOT quoted on the Nasdaq Stock Market, or even if so, has a price less than $5.00 per share; or (iv) is issued by a company that has been in business less than three years with net tangible assets less than $5 million.

The principal result or effect of being designated a "penny stock" is that securities broker-dealers participating in sales of our common stock will be subject to the "penny stock" regulations set forth in Rules 15-2 through 15g-9 promulgated under the Exchange Act. For example, Rule 15g-2 requires

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

## NOTE REGARDING THIS PROSPECTUS

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

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

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

In addition to historical information, this prospectus contains statements relating to our future business and/or results, including, without limitation, the statements under the captions "Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." These statements include certain projections and business trends that are "forward-looking" within the meaning of the United States Private Securities Litigation Reform Act of 1995 (the "PSLRA"). The safe harbor for forward-looking statements under the PSLRA does not apply to our company. You can identify these statements by the use of words like "may,"



"could," "should," "project," "believe," "anticipate," "expect," "plan," "estimate," "forecast," "potential," "intend," "continue" and variations of these words or comparable words. Forward-looking statements do not guarantee future performance and involve risks and uncertainties. Actual results will differ, and may differ materially, from projected results as a result of certain risks and uncertainties. These risks and uncertainties include, without limitation, those described under "Risk Factors" and those detailed from time to time in our filings with the SEC, and include, among others, the following:

- Our ability to raise additional funding and the amounts raised, if any;
- Our ability to successfully develop and commercialize any other proposed products, if any, derived from Homspera;
- A lengthy approval process and the uncertainty of FDA and other government regulatory requirements may have a material adverse effect on our ability to commercialize Radilex, Viprovex or any other proposed product, if any, derived from Homspera;
- Clinical trials may fail to demonstrate the safety and effectiveness of Radilex, Viprovex or any other proposed product, if any, derived from Homspera, which could have a material adverse effect on our ability to obtain government regulatory approval;
- The degree and nature of our competition;
- The shares and warrants that we accrue due to the delayed registration penalty provision under the October 2004 private placement;
- 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.

## USE OF PROCEEDS

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

## MARKET FOR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

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

| | 2006 | |
|---|---|---|
| | High | Low |

| | | |
|---|---|---|
| 1st Quarter (through April 4, 2006) | $ 0.35 | $ 0.20 |



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

| | 2004 | |
|---|---|---|
| | High | Low |
| 1st Quarter | $ 1.00 | $ 0.32 |
| 2nd Quarter* | 0.51 | 0.11 |
| 3rd Quarter | 0.19 | 0.09 |
| 4th Quarter | 0.40 | 0.15 |

* Effected 2-for-1 forward stock split in April 2004.

On April 4, 2006, 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 March 10, 2006. We have not paid any dividends on our common stock since inception and do not intend to do so in the foreseeable future.

## DIVIDEND POLICY

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

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

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Please note that the safe harbor for forward-looking statements under the Securities Act of 1933 and the Securities Exchange Act do not apply to our company. Our actual results could differ materially from those set forth as a result of general economic conditions and changes in the assumptions used in making such forward-looking statements. The following discussion and analysis of our financial condition and results of operations should be read together with the audited consolidated financial statements and accompanying notes and the other financial information

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

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

OVERVIEW

We were originally incorporated in the State of Delaware in June 1985 under the name Vocaltech, Inc. to develop, design, manufacture and market



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

GENERAL

IR BioSciences Holdings, Inc. is a development-stage biopharmaceutical company. Through our wholly owned subsidiary, ImmuneRegen BioSciences, Inc., we are engaged in the research and development of potential therapeutics for a number of applications. All potential therapeutics in development are based on Sar9, Met (O2)11-Substance P, an analog of the naturally occurring human neuropeptide Substance P. This neuropeptide can be found throughout the body, including in the airways of humans and many other species. We use the generic

name Homspera to refer to the synthetic Sar9, Met (O2)11-Substance P peptide. All of our research and development efforts are early, pre-clinical stage and Homspera has only undergone exploratory studies to evaluate its biological activity in small animals.

Currently, the majority of our development efforts are centered on two potential therapeutic applications for the active ingredient in Homspera. Radilex is being formulated specifically for the potential treatment of acute exposure to radiation. Viprovex is being formulated specifically for potential applications relating to the treatment of maladies caused by exposure to various chemical and biological agents. We are currently sponsoring ongoing pre-clinical studies in these areas, specifically two mouse radiation studies on the efficacy of Radilex in treating acute radiation exposure and a mouse study on the efficacy of Viprovex in treating exposure to anthrax. In addition, we have designed the protocols for additional radiation studies in mice using Radilex and an avian flu study in mice using Viprovex.

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

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

Our current potential drug candidates, Radilex and Viprovex and other technologies utilizing Homspera, are at early stages of development and may not be shown to be safe or effective and may never receive regulatory approval. Neither Radilex nor Viprovex nor our technologies utilizing Homspera have yet been tested in large animals or humans. There is no guarantee that regulatory



authorities will ever permit large animal or human testing of Radilex, Viprovex or any other potential products derived from Homspera. Even if such testing is permitted, none of Radilex, Viprovex or any other potential drug candidates, if any, derived from Homspera may be successfully developed or shown to be safe or effective.

The results of our preclinical studies and clinical trials may not be indicative of future clinical trial results. A commitment of substantial resources to conduct time-consuming research, preclinical studies and clinical trials will be required if we are to develop any commercial applications using Homspera or any derivates thereof. Delays in planned patient enrollment in our clinical trials may result in increased costs, program delays or both. None of our potential applications may prove to be safe or effective in clinical trials. Approval of the FDA or other regulatory approvals, including export license

permissions, may not be obtained and even if successfully developed and approved, our potential applications may not achieve market acceptance. Any applications resulting from our programs may not be successfully developed or commercially available for a number of years, if at all.

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

Prior to FDA approval, Radilex and Viprovex may become eligible for purchase by the U.S. government. Project BioShield legislation contains provisions enabling the U.S. Department of Health and Human Services, or HHS, to begin purchasing new medical countermeasures for the Strategic National Stockpile in advance of formal FDA approval. This provision, known as an Emergency Use Authorization, has already been implemented for other development stage medical countermeasures to weapons of mass destruction. In that our studies, in the opinion of management, indicate that Radilex may have efficacy in the treatment of the life-threatening effects of radiation exposure and Viprovex to exposure to various biological and chemical agents, we believe there may be interest by government agencies to stockpile Radilex and/or Viprovex if it is successfully developed. However, there is no assurance that any of such orders will be forthcoming and we have received no indication from Project BioShield or any other agency that it intends to purchase any quantities of Radilex or Viprovex.

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

PLAN OF OPERATIONS

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

Due to our liquidity and limited cash available our spending on research and development activities in the years ended December 31, 2004 and 2005 was limited. We spent approximately $113,731 and $150,091 in 2005 and 2004, respectively, in research and development activities related to the development of Radilex and Viprovex as potential protectants against the effects of chemical, biological, radiological and nuclear threats. From our inception in October 2002, we have spent $306,794 in research and development activities. These costs only include the manufacture and delivery of our drug by third party

manufacturers and payments to Contract Research Organizations for consulting



related to our studies and costs of performing such studies. Significant costs relating to research and development, such as consulting fees for Drs. Witten and Siegel, among others, have been classified in consulting fees for consistency of financial reporting.

We anticipate that during the next 12 months we will increase our research and development spending to a total of approximately $3,500,000 in an effort to further develop Radilex and Viprovex. The drug development, clinical trial and regulatory process is lengthy, expensive and uncertain and subject to numerous risks including, without limitation, the following risks discussed under "Risk Factors" - "All Our Applications Are All Derived From The Use Of Homspera. If Homspera Is Found To Be Unsafe Or Ineffective, Our Business Would Be Materially Harmed.," "If We Fail To Successfully Develop And Commercialize Products, We Will Have To Cease Operations.;" and, "The Lengthy Product Approval Process And Uncertainty Of Government Regulatory requirements may delay or prevent us from commercializing proposed products, and therefore adversely affect the timing and level of future revenues, if any."

PRODUCT RESEARCH AND DEVELOPMENT

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

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

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

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

We will need to generate significant revenues from product sales and or related royalties and license agreements to achieve and maintain profitability. Through December 31, 2005, we had no revenues from any product sales, royalties or licensing fees, and have not achieved profitability on a quarterly or annual basis. Our ability to achieve profitability depends upon, among other things, our ability to develop products, obtain regulatory approval for products under development and enter into agreements for product development, manufacturing and commercialization. Moreover, we may never achieve significant revenues or profitable operations from the sale of any of our potential products or technologies.



Our major research and development projects include:

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

We prepared the protocols for what we believe will be our final phase of rodent studies for a radiation sensitivity study on rodents to be conducted at the Oak Ridge National Laboratory in which we will attempt to validate our prior studies. This study commenced on February 28, 2006. We estimate that the study will be completed within 3 months at an estimated cost of $90,000. Upon completion of the aforementioned study we will prepare the protocols necessary for a non-human primate study to test the efficacy of Radilex as a potential treatment to acute radiation sickness. We expect this study to begin within the next 12 to 18 months. We believe that preliminary results will be available within 90 days from beginning of study, with analysis within an additional 60 to 90 days. We expect up to an additional $2,500,000 will be required to complete this study. We estimate the completion of this study will be in 18 to 24 months.

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

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

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We are sponsoring a series of studies with Hyperion Biotechnology Inc. at their laboratory facilities located at Brooks City-Base in San Antonio, Texas with the cooperation of the U.S. Air Force School of Aerospace Medicine (USAFSAM). The first of these studies was initiated in October 2005. Logistical considerations related to number of animals requiring exposure and performance of a full Viprovex dose-response curve within specified time limits following anthrax exposure required the experiment be performed in two sections, and it is incomplete at this time. The second half of the full dose-ranging experiment began in February, 2006. We estimate that the study will be completed within 3 months at an estimated cost of $51,450. If we are successful in achieving desirable results against anthrax, we intend to design the protocols and begin further studies for this and other indications, when capital is available. As we have only collected preliminary data and additional studies are required, we cannot predict when, if ever, a viable anthrax treatment can be commercialized. If we do not observe significant results or we lack the capital to further the development, we may abandon such research and development efforts; thereby limiting our future potential revenues.

OFF-BALANCE SHEET ARRANGEMENTS

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

REVENUES

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

COSTS AND EXPENSES

From our inception (October 30, 2002) through December 31, 2005, we have incurred losses of $11,799,134. These expenses were associated principally with equity-based compensation to employees and consultants, product development costs and professional services.



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

Our independent certified public accountants have stated in our Form 10-KSB/A as filed on March 30, 2006 that we have incurred a net loss and negative cash flows from operations of $4,591,107 and $1,884,113, respectively, for the year ended December 31, 2005. This loss, in addition to a lack of operational history, raises substantial doubt about our ability to continue as a going concern. In the absence of significant revenue and profits, and since we do not expect to generate significant revenues in the foreseeable future, we, in order to fund operations, will be completely dependent on additional debt and equity financing arrangements. There is no assurance that any financing will be sufficient to fund our capital expenditures, working capital and other cash requirements for the fiscal year ending December 31, 2006. No assurance can be given that any such additional funding will be available or that, if available, can be obtained on terms favorable to us. If we are unable to raise needed funds

on acceptable terms, we will not be able to develop or enhance our products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, we will not be able to continue operations.

Penalties for Late Registration
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In October 2004, we completed a private placement, whereby we sold an aggregate of $2,450,000 worth of units to accredited investors. Each unit was sold for $10,000 and consisted of (a) a number of shares of our common stock determined by dividing the unit price by $0.125, and (b) a warrant to purchase, at any time prior to the fifth anniversary following the date of issuance of the warrant, a number of shares of our common stock equal to fifty percent (50%) of the number of shares included within the unit, at a price equal to $0.50 per share of common stock. We issued in the private placement an aggregate of 19,600,000 shares of our common stock and warrants to purchase 9,800,000 shares of our common stock. In consideration of the investment, we granted to each investor certain registration rights and anti-dilution rights. We agreed to register these shares along with the shares underlying these warrants within ninety days from the closing date of the transaction, or we would incur a penalty equivalent to an additional 2% of the shares and warrants to be registered for every 30 days that we fail to complete this registration. This penalty amounts to an aggregate of 461,200 shares and 181,600 warrants per 30 day period until such a time as a registration statement that includes these shares and warrants is made effective.

At March 31, 2006, we have accrued liabilities to issue 6,625,907 shares of common stock and warrants to purchase an additional 2,608,987 shares for total shares of 9,234,895. The original values of these liabilities were $2,448,511 for the shares, and $744,177 for the warrants for a total of $3,188,691. Ad