

Edgar Filing: IR BIOSCIENCES HOLDINGS INC - Form 10KSB/A

IR BIOSCIENCES HOLDINGS INC  
Form 10KSB/A  
November 16, 2005

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

FORM 10-KSB/A  
AMENDMENT NO. 2

(X) Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2003.

OR

( ) Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

COMMISSION FILE NUMBER: 33-05384

IR BIOSCIENCES HOLDINGS, INC.

-----  
(Name of Small Business Issuer in its Charter)

DELAWARE

13-3301899

-----  
(State or Other Jurisdiction of  
Incorporation or Organization)

-----  
(I.R.S. Employer  
Identification No.)

8655 East Via De Ventura, Suite E-155

85258

-----  
(Address of Principal Executive Offices)

-----  
(Zip Code)

(480) 922-3926

-----  
(Issuer's Telephone Number, including Area Code)

Securities registered under Section 12(b) of the Exchange Act:

NONE

SECURITIES REGISTERED PURSUANT TO SECTION 12(G) OF THE EXCHANGE ACT:

COMMON STOCK, \$ 0.001 PAR VALUE PER SHARE

-----  
(Title of class)

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

Yes  
---

No X  
---

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B is not contained in this form, and no disclosure will be

Edgar Filing: IR BIOSCIENCES HOLDINGS INC - Form 10KSB/A

contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. [X]

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

The aggregate market value of the Registrant's issued and outstanding shares of common stock held by non-affiliates of the Registrant as of May 6, 2004 (based on the average of the bid and asked prices as reported by the NASD OTC Bulletin Board as of that date) was approximately \$2,309,569.

The number of shares outstanding of Registrant's Common Stock, par value \$0.001 as of May 3, 2004: 27,581,274.

Documents Incorporated by reference: None

Transitional Small Business Disclosure Format Yes --- No X ---

2

TABLE OF CONTENTS

Table with 2 columns: Item Description and Page. Includes sections for PART I (Item 1: Description of Business, page 3) and PART III (Item 13: Exhibits and Reports on Form 8-K, page 17; Signatures, page 18).

3

INTRODUCTORY NOTE

THE DISCUSSIONS IN THIS FORM 10-KSB MAY CONTAIN CERTAIN FORWARD-LOOKING STATEMENTS WITHIN THE MEANING OF SECTION 27A OF THE SECURITIES ACT OF 1933 AND SECTION 21E OF THE SECURITIES EXCHANGE ACT OF 1934. IN ADDITION, WHEN USED IN THIS FORM 10-KSB, THE WORDS "ANTICIPATES," "IN THE OPINION," "BELIEVES," "EXPECTS," AND SIMILAR EXPRESSIONS ARE INTENDED TO IDENTIFY FORWARD-LOOKING STATEMENTS. 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. ACTUAL FUTURE RESULTS COULD DIFFER MATERIALLY FROM THOSE DESCRIBED IN THE FORWARD-LOOKING STATEMENTS AS A RESULT OF 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. THE COMPANY CAUTIONS THE READER, HOWEVER, THAT THIS LIST OF RISK FACTORS MAY NOT BE EXHAUSTIVE. THE COMPANY EXPRESSLY DISCLAIMS ANY OBLIGATION OR UNDERTAKING TO

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

RELEASE PUBLICLY ANY UPDATES OR CHANGES TO THESE FORWARD-LOOKING STATEMENTS THAT MAY BE MADE TO REFLECT ANY ANTICIPATED OR UNANTICIPATED EVENTS OR CIRCUMSTANCES AFTER THE DATE OF SUCH STATEMENTS.

### PART I

#### ITEM 1. DESCRIPTION OF BUSINESS

Unless the context otherwise requires, references to "we," "us," the "Company" or "ImmuneRegen" mean IR BioSciences Holdings, Inc.

#### BUSINESS DEVELOPMENT

Our company, IR BioSciences Holdings, Inc., is a Delaware corporation and, until July 2001, was engaged in the business of assisting unaffiliated early-stage development and small to mid-sized emerging growth companies with financial and business development services, including raising capital in private and public offerings. During 2001, we failed to meet our revenue targets. On July 27, 2001, a majority interest in our company was acquired by a private investor, and we installed new management and adopted a new business plan. The immediate action taken regarding this new business plan was to discontinue our then current operations effective July 27, 2001.

On July 2, 2003, our company and ImmuneRegen Biosciences, Inc., a privately-held Delaware corporation ("ImmuneRegen"), entered into and consummated an Agreement and Plan of Merger (the "Merger"). In accordance with the Merger, on July 2, 2003, we acquired ImmuneRegen in exchange for 10,531,585 shares of our common stock. The transaction contemplated by the Agreement was intended to be a "tax-free" reorganization pursuant to the provisions of Section 351 and 368(a)(1)(A) of the Internal Revenue Code of 1986, as amended. On August 29, 2003, the Registrant's name was changed from GPN Network, Inc. to IR BioSciences Holdings, Inc.

#### CORPORATE STRUCTURE

IR BioSciences Holdings is a publicly-traded entity and has one wholly-owned subsidiary: ImmuneRegen BioSciences, Inc. ImmuneRegen BioSciences, Inc. is a Delaware Corporation, and was incorporated on October 30, 2002. Currently, all of our Company's operations are conducted by ImmuneRegen BioSciences, Inc.

#### BUSINESS DESCRIPTION

ImmuneRegen BioSciences, Inc. is a biotechnology company engaged in the research and development of applications utilizing modified substance P, a naturally occurring immunomodulator. Derived from homeostatic substance P, ImmuneRegen has named its proprietary compound "Homspera." Currently, ImmuneRegen holds two patents and four provisional patents in the United States. Additionally, ImmuneRegen holds a patent with the European Union and Australia and is seeking to extend its patents into Canada and, possibly, Japan.

ImmuneRegen's initial areas of focus will be in continuing development of several applications for use in improving pulmonary function and stimulating the immune system. These applications have been derived from research studies and positive results from laboratory tests conducted by management over the past nine years.

With the assistance of our U.S. Food and Drug Administration ("FDA") consultants, Synergos, Inc., ImmuneRegen plans to apply for Investigational New Drug ("IND") approval from the FDA. Based on ImmuneRegen's past test results and continuing studies, ImmuneRegen believes that its IND may be activated, allowing it to begin its human clinical trials using the Homspera compound as a treatment for lung injury caused by acute respiratory disease syndrome ("ARDS"), an often

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

fatal disease.

ImmuneRegen's goal is to enter into overseas licensing and royalty agreements for its applications while awaiting approval by the FDA in the United States.

4

Once approval has been obtained by the FDA, ImmuneRegen hopes to further expand its sales efforts internationally and will attempt to begin to generate sales domestically through the licensing and the direct sales of its products in the United States. A goal is to strategically align itself with larger pharmaceutical and other biotechnology and medical research companies, which ImmuneRegen believes may enhance its ability to succeed in reaching the objectives of bringing its applications to the marketplace. If FDA approval is granted, ImmuneRegen intends to seek to establish license agreements and relationships domestically that will bring Homspera to those in need of it.

Substance p

-----

Substance P, first isolated in 1931, is a bioactive 11-amino acid peptide belonging to a group of neurokinins (small peptides that are broadly distributed in the central nervous system and peripheral nervous system). Substance P has been found to be involved in many physiological processes including pain modulation, smooth muscle contraction, blood pressure control, kidney function and water homeostasis. The peptide is widely distributed in numerous tissues and body fluids including the central and peripheral nervous system, gastrointestinal tract, visual system and circulatory system.

In the 1950s, substance P was considered to be the neurotransmitter for primary sensory afferent fibers, or the pain transmitter. By the 1970s, the biochemical properties of purified substance P were found to be a proteinaceous substance composed of amino acids that, subsequently, could be synthetically derived.

Since then, substance P has been extensively studied by researchers and scientists worldwide because of its many general physiological effects (smooth muscle contraction, inflammation, neurotransmission, blood vessel dilation, histamine release, and activation of the immune system) including its potential to stimulate epithelial growth; heal ulcers and ocular wounds; and, as a new approach to dulling anxiety and relieving depression and stress.

ImmuneRegen's patents and continued substance P research are derived from discoveries made during research funded by the Air Force Office of Scientific Research in the early 1990s. During this research ImmuneRegen's founders, Drs. Witten and Harris, observed that the exposure of animals to jet fuels resulted in pathological changes in the lung and immune systems of those exposed. It was also observed that such exposure resulted in depletion of substance P from the lungs of the animals. These studies further showed that the administration of substance P may help prevent and reverse the effects of jet fuel exposure in the lungs, as well as protect and regenerate the immune system. The immune findings led to early research on the treatment of exposure to acute radiation and on the possible reversal of lung damage caused by ARDS and cigarette smoke.

Research & Development

-----

Homspera is a proprietary compound created by modifying substance P. Based on initial findings and ongoing research studies, ImmuneRegen intends to initially focus on developing treatments for acute radiation syndrome ("ARS"), ARDS and hair replacement related to loss due to traditional anti-cancer treatments.

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

Additionally, management believes that Homspera may be proven to provide applications for: 1) lessening lung damage caused by cigarette smoke and other toxicants related to air pollution; 2) the treatment of respiratory diseases associated with chronic obstructive pulmonary disease ("COPD"); 3) the treatment of lung and other cancers; 4) hair replacement; and, 5) the treatment of animals through the development of similar applications for use in veterinary medicine.

In the future, ImmuneRegen believes that it may be able to increase and strengthen its market position in the following ways: (i) working with the FDA to obtain the approval of the Homspera and future developments; (ii) investigating foreign markets for the use of Homspera and future products; and, (iii) continuing its current research into developing new applications.

ImmuneRegen has established a pilot manufacturing facility at its lab headquarters in Tucson, Arizona for the production of immune-based therapies. ImmuneRegen expects these facilities to be adequate to supply limited clinical trial quantities for its products under development. Additional manufacturing capacity will be needed for commercial scale production, if these therapies are approved for commercial sale.

For the manufacture of the applications under development, ImmuneRegen obtains synthetic peptides from third party manufacturers. ImmuneRegen believes that synthesized version of substance P is readily available at low cost from several life science and technology companies that provide biochemical and organic chemical products and kits used in scientific and genomic research, biotechnology, pharmaceutical development and the diagnosis of disease and chemical manufacturing. ImmuneRegen believes that the synthetic substance P and other materials necessary to produce Homspera are readily available from various sources, and several suppliers are capable of supplying substance P in both clinical and commercial quantities. These suppliers also store and ship the product as well.

ImmuneRegen expects that its products will use an inhaler (puffer) device to deliver Homspera to the user. To develop, manufacture and test an inhaler device ImmuneRegen hopes to partner with a drug development and chemical services company that offers services ranging from pre-clinical and toxicology studies to clinical trial support and manufacturing services. ImmuneRegen believes that such a partnership may enable it to decrease the time-to-market for its products and to increase its productivity.

5

### Our Products

-----

Based on its initial research findings, ImmuneRegen plans to initially develop applications using Homspera for:

- o The treatment for ARS;
- o The treatment of ARDS; and,
- o Hair loss replacement/attenuation due to its traditional anti-cancer treatments.

While performing the necessary research studies and due diligence to gain FDA approval of Homspera, ImmuneRegen hopes to enter into various license agreements, joint ventures and perform additional research overseas.

In conjunction with these initial areas ImmuneRegen plans to continue research

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

and data collection, perform further research studies, and hopes to enter into license agreements overseas for:

- o Therapies that may lessen lung damage caused by cigarette smoke and other toxicants related to air pollution;
- o Providing a possible solution to the hair replacement industry; and,
- o The treatment of animals through the possible development of similar applications for use in veterinary medicine.

Looking ahead, based on collected preliminary research data, ImmuneRegen believes it may be able to develop applications for:

- o Reducing the risk of cancer development;
- o Prevention of the spread and metastasis of cancer;
- o The treatment of lung and other cancers;
- o Enhancing an immune response to a viral infection; and,
- o Boosting a suppressed or failing immune system, which has direct applications in the treatment of the common cold, AIDS, food poisoning and slowing the effects of aging.

### Immuneregen's Strategy

-----

ImmuneRegen's strategy is to develop, test and obtain regulatory approval for various applications using Homspera in a diverse array of applications. The first two regulatory approvals ImmuneRegen hopes to obtain are in the United States and Europe. ImmuneRegen is currently investigating regulatory and other requirements in these countries, as well as others. ImmuneRegen is also evaluating other market for distribution of Homspera and hopes to secure potential strategic partners and licensees in these foreign markets.

ImmuneRegen's strategy is focused on the following major steps:

#### ESTABLISHING AND FORMALIZING STRATEGIC PARTNERING RELATIONSHIPS.

ImmuneRegen's aim is to establish relationships with industry leaders in the pharmaceutical and medical device industries for application-specific sales and distribution of its techniques and products, both domestic and international. ImmuneRegen believes this may have the effect of generating revenues in under twelve months after funding in the form of license agreements with companies in Europe and other countries, while awaiting possible FDA approval for sales in the United States to begin.

#### ACCELERATING CURRENT RESEARCH EFFORTS.

ImmuneRegen is working on capturing the full benefit of the Homspera technology in applications relating to the aforementioned fields. Further, the research that has produced Homspera could be applicable to other processes.

#### EXPANDING PRODUCTION FACILITY CAPACITY.

ImmuneRegen intends to operate a laboratory facility in Tucson, Arizona, which is equipped with state-of-the-art culture equipment, instrumentation and storage systems. ImmuneRegen intends to implement expansion plans if it receives its IND

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

from the FDA.

6

### EXPANDING SALES, PRODUCTION AND ADMINISTRATIVE RESOURCES.

Sales, increased research, and foreign affiliations will require more resources by ImmuneRegen. ImmuneRegen hopes these will be supplied through third party relationships and increases to staff as necessary.

### SUPPLEMENTING AND LEVERAGING EXISTING ADVISORY RELATIONSHIPS.

Pharmaceutical, biotechnology and corporate companies are a primary channel for introducing and distributing new products. To facilitate the marketing strategies outlined above, ImmuneRegen intends to supplement and leverage its existing relationships.

In the future, ImmuneRegen believes that it may be able to increase and strengthen its market position in the following ways: (i) working with the FDA to obtain the approval of the Homspera and future developments; (ii) investigating foreign markets for the use of Homspera and future products; and, (iii) continuing its current research into the science of attenuating ailments.

### Manufacturing

-----

ImmuneRegen has established a pilot manufacturing facility at its lab headquarters in Tucson, Arizona for the production of immune-based therapies. ImmuneRegen expects these facilities to be adequate to supply limited clinical trial quantities for our products under development. Additional manufacturing capacity will be needed for commercial scale production, if these therapies are approved for commercial sale.

For the manufacture of the applications under development, ImmuneRegen obtains synthetic peptides from third party manufacturers. ImmuneRegen believes a synthesized version of substance P is readily available at low cost from several life science and technology companies that provide biochemical and organic chemical products and kits used in scientific and genomic research, biotechnology, pharmaceutical development and the diagnosis of disease and chemical manufacturing. ImmuneRegen believes that the synthetic substance P and other materials necessary to produce Homspera are readily available from various sources, and several suppliers are capable of supplying substance P in both clinical and commercial quantities. These suppliers also store and ship the product as well.

ImmuneRegen's products will use an inhaler (puffer) device to deliver Homspera to the user. To develop, manufacture and test an inhaler device, ImmuneRegen hopes to partner with a full-service drug development and chemical services company that offers services ranging from pre-clinical and toxicology studies to clinical trial support and manufacturing services. ImmuneRegen believes such a partnership may enable it to decrease the time-to-market for its products and to increase its productivity.

### Government Regulation

-----

Our development, manufacture and potential sale of therapeutics are subject to extensive regulation by United States and foreign governmental authorities. In particular, pharmaceutical products are subject to rigorous preclinical and clinical testing and to other approval requirements by the FDA in the United

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

States under the Food, Drug and Cosmetic Act, and by comparable agencies in most foreign countries.

As an initial step in the FDA regulatory approval process, preclinical studies are typically conducted in animals to identify potential safety problems. For certain diseases, animal models exist that are believed to be predictive of human efficacy. For such diseases, a drug candidate is tested in an animal model. The results of the studies are submitted to the FDA as a part of the Investigational New Drug application (IND) that is filed to comply with FDA regulations prior to commencement of human clinical testing in the U.S. For diseases for which no appropriately predictive animal model exists, no such results can be filed. As a result, no IN VIVO evidence of efficacy would be available until such compounds progress to human clinical trials.

Clinical trials are typically conducted in three sequential phases, although the phases may overlap. In Phase I, which frequently begins with the initial introduction of the drug into healthy human subjects prior to introduction into patients, the compound will be tested for safety, dosage tolerance, absorption, bioavailability, biodistribution, metabolism, excretion, clinical pharmacology and, if possible, for early information on effectiveness. Phase II typically involves studies in a small sample of the intended patient population to assess the efficacy and duration of the drug for a specific indication, to determine dose tolerance and the optimal dose range and to gather additional information relating to safety and potential adverse effects. Phase III trials are undertaken to further evaluate clinical safety and efficacy in an expanded patient population at geographically dispersed study sites, to determine the overall risk-benefit ratio of the drug and to provide an adequate basis for physician labeling. Each trial is conducted in accordance with certain standards under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Further, each clinical study must be evaluated by an independent Institutional Review Board at the institution at which the study will be conducted. The Institutional Review Board will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution.

Data from preclinical testing and clinical trials are submitted to the FDA in a New Drug Application (NDA) for marketing approval. The process of completing clinical testing and obtaining FDA approval for a new drug is likely to take a number of years and require the expenditure of substantial resources. Preparing an NDA involves considerable data collection, verification, analysis and

7

expense, and there can be no assurance that approval will be granted on a timely basis, if at all. The approval process is affected by a number of factors, including the severity of the disease, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. The FDA may deny an NDA if applicable regulatory criteria are not satisfied or may require additional testing or information. Among the conditions for marketing approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to the FDA's CGMP regulations, which must be followed at all times. In complying with standards set forth in these regulations, manufacturers must continue to expend time, monies and effort in the area of production and quality control to ensure full mechanical compliance. Manufacturing establishments, both foreign and domestic, also are subject to inspections by or under the authority of the FDA and by or under the authority of other federal, state or local agencies.

Even after initial FDA approval has been obtained, further studies, including



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

post-marketing studies, may be required to provide additional data on safety and will be required to gain approval for the use of a product as a treatment for clinical indications other than those for which the product was initially tested. Also, the FDA will require post-marketing reporting to monitor the side effects of the drug. Results of post-marketing programs may limit or expand further marketing of the drug products. Further, if there are any modifications to the drug, including changes in indication, manufacturing process, labeling or manufacturing facilities, an NDA supplement may be required to be submitted to the FDA.

The Orphan Drug Act provides incentives to drug manufacturers to develop and manufacture drugs for the treatment of diseases or conditions that affect fewer than 200,000 individuals in the United States. Orphan drug status can also be sought for diseases or conditions that affect more than 200,000 individuals in the United States if the sponsor does not realistically anticipate its product becoming profitable from sales in the United States. Under the Orphan Drug Act, a manufacturer of a designated orphan product can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for that product for the orphan indication. While the marketing exclusivity of an orphan drug would prevent other sponsors from obtaining approval of the same compound for the same indication, it would not prevent other types of drugs from being approved for the same use. We may apply for orphan drug status for the use of Homospora for certain indications.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, a sponsor may be granted marketing exclusivity for a period of time following FDA approval of certain drug applications if FDA approval is received before the expiration of the patent's original term. This marketing exclusivity would prevent a third party from obtaining FDA approval for a similar or identical drug through an Abbreviated New Drug Application, which is the application form typically used by manufacturers seeking approval of a generic drug. The statute also allows a patent owner to extend the term of the patent for a period equal to one-half the period of time elapsed between the filing of an IND and the filing of the corresponding NDA plus the period of time between the filing of the NDA and FDA approval. We may seek the benefits of this statute, but there can be no assurance that we will be able to obtain any such benefits.

Whether or not FDA approval has been obtained, approval of a drug product by regulatory authorities in foreign countries must be obtained prior to the commencement of commercial sales of the product in such countries. Historically, the requirements governing the conduct of clinical trials and product approvals, and the time required for approval, have varied widely from country to country.

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

### FACILITIES

The Company has a lease agreement for 1,440 square feet of office space in Scottsdale, Arizona. The lease expires August 31, 2004. Rent expense is \$2,734 per month.

### EMPLOYEES

As of December 31, 2003, ImmuneRegen had one full-time employee and three contract employees. Our sole full time employee is our Chief Executive Officer, Michael K. Wilhelm. None of its employees are covered by a collective bargaining agreement.

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

### RISK FACTORS

In evaluating our business, you should consider the following discussions of risks, in addition to other information contained in this report as well as our other public filings with the Securities and Exchange Commission. Any of the following risks could materially adversely affect our business, financial condition, results of operations and prospects.

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

As December 31, 2003, our working capital totaled approximately \$(866,040). We have incurred a substantial net loss for the period from our inception in

8

October 2002 to December 31, 2003, and currently experiencing negative cash flow. We expect to continue to experience negative cash flow and operating losses through at least 2004 and possibly thereafter. As a result, we will need to generate significant revenues to achieve profitability. If our revenues grow more slowly than we anticipate, or if our operating expenses exceed our expectations, we may experience reduced profitability.

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

We are focused on product development and have not generated any revenue to date. We have incurred operating losses since our inception. Our net loss for the twelve months ended December 31, 2003 was \$1,856,702. As of December 31, 2003, we had an accumulated deficit of \$1,902,620.

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

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

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

Our independent certified public accountants have stated in their report included in this Form 10-KSB that the Company has incurred a net loss and negative cash flows from operations of \$1,856,702 and \$996,890, respectively, for the year ended December 31, 2003, 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

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

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.

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

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

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:

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

9

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

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

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

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. As of December 31, 2003, our cash and cash equivalents totaled approximately \$10,534. Based on our current plans, we believe these financial resources, and interest earned thereon, will be sufficient to meet our operating expenses and capital requirements for at least the next 30 days. 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, 2004. No assurance can be given that any such additional funding will be available or that, if available, can be obtained on terms favorable to us. If we are unable to raise needed funds on acceptable terms, we will not be able to develop or enhance our products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, we will not be able to continue operations.

We expect to require substantial additional funds in order to finance our drug discovery and development programs, fund operating expenses, pursue regulatory clearances, develop manufacturing, marketing and sales capabilities, and prosecute and defend our intellectual property rights. We may seek additional funding through public or private financing or through collaborative arrangements with strategic partners.

You should be aware that in the future:

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

If we cannot raise additional funds when needed, or on acceptable terms, we will not be able to continue to develop our drug candidates. We require substantial working capital to fund our operations. Since we do not expect to generate significant revenues in the foreseeable future, in order to fund operations, we will be completely dependent on additional debt and equity financing arrangements. There is no assurance that any financing will be sufficient to fund our capital expenditures, working capital and other cash requirements for the next 12 months. Our working capital as of December 31, 2004 was \$(866,040). No assurance can be given that any such additional funding will be available or that, if available, can be obtained on terms favorable to us. If we are unable to raise needed funds on acceptable terms, we will not be able to develop or enhance our products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, we will not be able to continue operations.

ALL OUR APPLICATIONS ARE ALL DERIVED FROM THE USE OF HOMSPERA. IF HOMSPERA IS FOUND TO BE UNSAFE OR INEFFECTIVE, WE WOULD HAVE NO POTENTIAL SOURCE OF REVENUES AND MAY BE REQUIRED TO CEASE OPERATIONS.

All our potential applications are derived from the use of Homspira. In addition, we expect to utilize Homspira in the development of any future products we market. If these current or future Homspira-based products are found to be unsafe or ineffective due to the use of Homspira, we may have to modify or cease production of the products. As all of our applications utilize or will utilize Homspira, any findings that Homspira is unsafe or ineffective would

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

severely harm our Homspera-based business operations, since all of our primary revenue sources would be negatively affected by such findings. In such an event, we may be required to cease operations.

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

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

Our therapies and technologies utilizing Homspera is at early stages of development and may not be shown to be safe or effective and may never receive regulatory approval. Our technologies utilizing Homspera have not yet been tested in humans. Regulatory authorities may not permit human testing of potential products based on these technologies. Even if human testing is permitted, any potential products based on Homspera may not be successfully developed or shown to be safe or effective.

The results of our preclinical studies and clinical trials may not be indicative or future clinical trial results. A commitment of substantial resources to conduct time-consuming research, preclinical studies and clinical trials will be

10

required if we are to develop any products. Delays in planned patient enrollment in our clinical trials may result in increased costs, program delays or both. None of our potential products may prove to be safe or effective in clinical trials. Approval of the United States Food and Drug Administration, the FDA, or other regulatory approvals, including export license permissions, may not be obtained and even if successfully developed and approved, our potential products may not achieve market acceptance. Any products resulting from our programs may not be successfully developed or commercially available for a number of years, if at all.

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

THE MARKET FOR TREATING ACUTE RADIATION SYNDROME IS UNCERTAIN AND IF WE ARE UNABLE TO SUCCESSFULLY COMMERCIALIZE RADILEX, WE WILL NOT RECOGNIZE A SIGNIFICANT PORTION OF OUR PLANNED REVENUES.

We do not believe any drug has ever been approved and commercialized for the treatment of severe acute radiation injury. In addition, the incidence of large-scale exposure to nuclear or radiological events has been low. Accordingly, even if Radilex, our lead drug candidate to treat Acute Radiation Syndrome (ARS), is approved by the FDA, we cannot predict with any certainty the

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

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

THE LENGTHY PRODUCT APPROVAL PROCESS AND UNCERTAINTY OF GOVERNMENT REGULATORY REQUIREMENTS MAY DELAY OR PREVENT US FROM COMMERCIALIZING PROPOSED PRODUCTS, 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. Clinical trials are required and the marketing and manufacturing of our applications are subject to rigorous testing procedures. Significant delays in clinical trials will impede our ability to commercialize our applications and generate revenue and could significantly increase our development costs. The commencement and completion of clinical trials for our Homspera-based applications or any of our applications could be delayed or prevented by a variety of factors, including:

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

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

- o labeling and advertising requirements, restrictions or limitations, including the inclusion of warnings, precautions, contra-indications or use limitations that could have a material impact on the future profitability of our applications;
- o testing and surveillance to monitor our future products and their continued compliance with regulatory requirements;

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

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

products;

- o suspending manufacturing; or
- o withdrawing marketing clearance.

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

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

The FDA has not designated expanded access protocols for Homspera as "treatment" protocols. The FDA may not determine that Homspera meets all of the FDA's criteria for use of an investigational drug for treatment use. Even if Homspera is allowed for treatment use, third party payers may not provide reimbursement for the costs of treatment with Homspera. The FDA also may not consider Homspera to be an appropriate candidate for 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 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 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 APPLICATIONS, WHICH COULD PREVENT OR SIGNIFICANTLY DELAY REGULATORY APPROVAL.

Prior to receiving approval to commercialize any of our applications or therapies, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA and other regulatory authorities in the United States and abroad, that our applications are both safe

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

and effective. We will need to demonstrate our applications' efficacy and monitor their safety throughout the process. If any future clinical trials are unsuccessful, our business and reputation would be harmed and our stock price would be adversely affected.

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

12

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

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

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

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

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



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

- o failure to raise additional funds.

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

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

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

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

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

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

We may enter into arrangements with contract manufacturing companies in order to meet requirements for our products or to attempt to improve manufacturing efficiency. If we choose to contract for manufacturing services, we may encounter costs, delays and/or other difficulties in producing, packaging and distributing our clinical trials and finished product. Further, contract manufacturers must also operate in compliance with the GMP requirements; failure to do so could result in, among other things, the disruption of our product supplies. Our potential dependence upon third parties for the manufacture of our proposed products may adversely affect our profit margins and our ability to develop and deliver proposed products on a timely and competitive basis. For the manufacture of the applications under development, we obtain synthetic peptides from third party manufacturers. A synthesized version of Homspira is readily available at low cost from several life science and technology companies that provide biochemical and organic chemical products and kits used in scientific and genomic research, biotechnology, pharmaceutical development and the diagnosis of disease and chemical manufacturing. If any of these proposed

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

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

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

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

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

Our ability to market and commercialize Homspera depends on the acceptance and utilization of Homspera by the medical community. We will need to develop commercialization initiatives designed to increase awareness about us and Homspera among targeted audiences, including public health activists and community-based outreach groups in addition to the investment community.

Currently, we have not developed any such initiatives. Without such acceptance of Homspera, the product upon which we expect to be substantially dependent, we may not be able to successfully commercialize Homspera or generate revenue.

PRODUCT LIABILITY EXPOSURE MAY EXPOSE US TO SIGNIFICANT LIABILITY OR COSTS, 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 avoids liability exposure, significant costs could be incurred that could hurt our

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

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 or have obtained a license to 4 issued U.S. and foreign patents and 8 pending U.S. and foreign patent applications. Our success will depend in part on our ability to obtain additional United States and foreign patent protection for our drug candidates and processes, preserve our trade secrets and operate without infringing the proprietary rights of third parties. We place considerable importance on obtaining patent protection for significant new technologies, products and processes.

Our long-term success largely depends on our ability to market technologically competitive processes and products. If we fail to obtain or maintain these protections we may not be able to prevent third parties from using our proprietary rights. Our currently pending or future patent applications may not result in issued patents. In the United States, patent applications are confidential until patent applications are published or the patent is issued, and because third parties may have filed patent applications for technology covered by our pending patent applications without us being aware of those applications, our patent applications may not have priority over any patent applications of others. In addition, our issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products or provide us with any competitive advantage. If a third party initiates litigation regarding our patents, and is successful, a court could revoke our patents or limit the scope of coverage for those patents. Legal standards relating to the validity of patents covering pharmaceutical and biotechnology inventions and the scope of claims made under such patents are still developing. In some of the countries in which we intend to market our products, pharmaceuticals are either not patentable or have only recently become

14

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

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

breach will be insufficient to allow us to recover our costs. Furthermore, our trade secrets, know-how and other technology may otherwise become known or be independently discovered by our competitors.

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

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

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

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

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

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

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

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

financial results.

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

We may be required to incur significant costs to comply with current or future environmental laws and regulations. Although we do not currently manufacture commercial quantities of our proposed products, we do produce limited quantities

15

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

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

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

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

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

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

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

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

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

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

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

may have the effect of temporarily or permanently driving down the price of our common stock. In addition, the stock market from time to time experiences extreme price and volume fluctuations which particularly affect the market prices for emerging and life sciences companies, such as ours, and which are often unrelated to the operating performance of the affected companies. For example, our stock price has ranged from \$0.01 to \$4.50 between January 1, 2003 and December 31, 2003.

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

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

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

Our common stock is currently traded on a limited basis on the OTC Bulletin Board (the "OTCBB") under the symbol "IRBO". The OTCBB is an inter-dealer, Over-The-Counter market that provides significantly less liquidity than the NASDAQ Stock Market. Quotes for stocks included on the OTCBB are not listed in the financial sections of newspapers as are those for the NASDAQ Stock Market. Therefore, prices for securities traded solely on the OTCBB may be difficult to obtain and holders of common stock may be unable to resell their securities at or near their original offering price or at any price. The NASD has enacted recent changes that limit quotations on the OTC Bulletin Board to securities of issuers that are current in their reports filed with the Securities and Exchange Commission. The effect on the OTC Bulletin Board of these rule changes and other proposed changes cannot be determined at this time.

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

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.

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.

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.

Edgar Filing: IR BIOSCIENCES HOLDINGS INC - Form 10KSB/A

PART III

ITEM 13. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a) Financial Statements, Financial Statement Schedules and Exhibits

INDEPENDENT AUDITOR'S REPORT.

CONSOLIDATED BALANCE SHEET AS OF DECEMBER 31, 2003.

Consolidated Statements of Operations for the twelve months ended December 31, 2003 and from the date of inception (October 30, 2002) to December 31, 2003.

Consolidated Statement of Stockholder's Equity for the period from the date of inception (October 30, 2002) to December 31, 2003.

Consolidated Statements of Cash Flows for the twelve months ended December 31, 2003 and from the date of inception (October 30, 2002) to December 31, 2003.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS.

EXHIBITS

Exhibit Number	Description
-----	-----
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbannes Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbannes Oxley Act of 2002
32.1	Certification Pursuant To 18 U.S.C.ss.1350, As Adopted Pursuant To Section 906 Of The SARBANES-OXLEY ACT OF 2002
32.2	Certification Pursuant To 18 U.S.C.ss.1350, As Adopted Pursuant To Section 906 Of The SARBANES-OXLEY ACT OF 2002

(b) Form 8K/A filed as of December 29, 2003 to amend the Company's form 8K filed on July 7, 2003 pursuant to a change in control of the Company.

18

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on November 16, 2005

IR BIOSCIENCES HOLDINGS, INC.

By: /s/ Michael K. Wilhelm

-----  
Michael K. Wilhelm  
President and Chief Executive Officer



