

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

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

FORM 10-QSB/A  
AMENDMENT NO. 2

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D. C. 20549

(X) Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the quarterly period ended March 31, 2004

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

COMMISSION FILE NUMBER: 033-05384

IR BIOSCIENCES HOLDINGS, INC.

(Exact name of Registrant as specified in its charter)

----- Delaware ----- (State or other jurisdiction of incorporation or organization)	13-3301899 ----- (I.R.S. Employer Identification No.)
---	--

----- 8655 East Via De Ventura, Suite E-155, Scottsdale, Arizona ----- (Address of principal executive offices)	85258 ----- Zip Code
--	----------------------------

----- Registrant's telephone number, including area code -----	(480) 922-3926 -----
--	-------------------------

N/A

---  
(Former name, former address and former fiscal year,  
if changed since last report)

Indicate by check mark whether Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding twelve 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 X NO  
--- ---

The number of shares outstanding of Registrant's common stock as of May 6, 2004 was 28,194,500.

IR BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 2. Management's Discussion and Analysis of Financial Condition or Plan of Operation.....13

PART II. OTHER INFORMATION

Item 6. Exhibits and Reports on Form 8-K.....23
Signatures.....24

PART I. FINANCIAL INFORMATION

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATIONS.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The following information should be read in conjunction with the financial statements and the notes thereto. 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 QUARTERLY REPORT FORM 10-QSB 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 DESCRIBED UNDER "RISK FACTORS" AND ELSEWHERE IN THIS QUARTERLY REPORT ON FORM 10-Q. 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 REPORT

The following information should be read in conjunction with the financial statements and the notes thereto. 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.

Overview

Our company, IR BioSciences Holdings, Inc., is a Delaware corporation and, until July 2001, was engaged in the business, through its subsidiaries, affiliates and strategic alliances, of assisting unaffiliated early-stage development and small

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

to mid-sized emerging growth companies with financial and business development services, including raising capital in private and public offerings. During 2001, due in large part to the decreased availability of investment capital to our then target market of Internet related, small growth companies, 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.

ImmuneRegen 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.

13

Our 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., we plan to apply for Investigational New Drug ("IND") approval from the FDA. Based on our past test results and continuing studies, we believe that the IND may be activated, allowing us to begin human clinical trials using the Homspera compound as a treatment for lung injury caused by acute respiratory disease syndrome ("ARDS").

Our goal is to enter into overseas licensing and royalty agreements for its applications while awaiting approval by the FDA in the United States. Once approval has been obtained by the FDA, we hope to further expand our sales efforts internationally and will attempt to begin to generate sales domestically through the licensing and the direct sales of our products in the United States. Our goal is to strategically align ourselves with larger pharmaceutical and other biotechnology and medical research companies, which we believe may enhance our ability to succeed in reaching the objectives of bringing its applications to the marketplace. If FDA approval is granted, we intend to seek to establish license agreements and relationships domestically that will bring Homspera to those in need of it.

We have established a pilot manufacturing facility at our lab headquarters in Tucson, Arizona for the production of immune-based therapies. We expect 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.

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

For the manufacture of the applications under development, we obtain synthetic peptides from third party manufacturers. We believe 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. 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. These suppliers also store and ship the product as well.

We expect that our products will use an inhaler (puffer) device to deliver Homspera to the user. To develop, manufacture and test an inhaler device we hope 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. We believe that such a partnership may enable us to decrease the time-to-market for our products and to increase our productivity.

### RESULTS OF OPERATIONS - THREE MONTHS ENDED MARCH 31, 2004

#### Revenue

-----

We are in the development stage and have no revenue.

#### Selling, General and Administrative Expenses

-----

Selling, general and administrative expenses were \$931,074 for the three months ended March 31, 2004. This amount consists primarily of non-cash compensation of \$698,827 and professional fees of \$87,114. We expect these costs to increase in the coming year as we continue to seek further financing, implement our plan of operation, and as we build out our administrative and operational infrastructure.

#### Interest Expense

-----

Interest expense was \$304,078 for the three months ended March 31, 2004. This amount consists of amortization of the beneficial conversion feature of notes payable of \$287,241 and interest on the notes payable of \$16,837. The Company expects interest expense to increase in the next twelve months if additional debt financing is secured. Such debt would likely to contain beneficial conversion features which will contribute further to our interest expense as the value of these beneficial conversion features is amortized.

14

#### Net Loss

-----

For the reasons stated above, the Company had a net loss of (\$1,235,152) or (\$0.05) per share for the three months ended March 31, 2004. We expect further losses for the foreseeable future until our products can be successfully developed and marketed.

#### Liquidity and Capital Resources

-----

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

At March 31, 2004, we had current assets of \$24,855, consisting of cash of \$12,555 and prepaid services of \$12,300. Also at March 31, 2004, we had current liabilities of \$1,385,057, consisting of accounts payable and accrued liabilities of \$587,887, demand loans payable of \$376,000, notes payable due within twelve months of \$421,170. This results in negative working capital of (\$1,360,202). During the three months ended March 31, 2004, the Company used cash in operating activities of (\$134,179). From the date of inception (October 30, 2002) to March 31, 2004, the Company has had a net loss of (\$3,137,772) and has used \$1,167,342 in operating activities.

The Company currently has no revenue. There is no guarantee that our business model will be successful, or that we will be able to generate sufficient revenue to fund future operations. As a result, we expect our operations to continue to use net cash, and that we will be required to seek additional debt or equity financings during the coming quarters. Since Inception, the Company has financed its operations through debt and equity financing. While we have raised capital to meet our working capital and financing needs in the past, additional financing is required in order to meet our current and projected cash flow deficits from operations and development. It is expected that in order to implement its business plan, the Company will require additional capital. There can be absolutely no assurance that we will be able to consummate future debt or equity financings in a timely manner on a basis favorable to us, or at all.

By adjusting its operations and development to the level of capitalization, management believes it has sufficient capital resources to meet projected cash flow deficits through the next twelve months. However, if thereafter, we are not successful in generating sufficient liquidity from operations or in raising sufficient capital resources, on terms acceptable to us, this could have a material adverse effect on our business, results of operations, liquidity and financial condition.

### Product Research and Development

-----

We anticipate performing further research and development of the applications of our proprietary compound "Homspera" during the next twelve months. These projected expenditures are dependent upon our generating revenues and obtaining sources of financing in excess of our existing capital resources. There is no guarantee that we will be successful in raising the funds required or generating revenues sufficient to fund the projected costs of research and development during the next twelve months

### Acquisition of Plant and Equipment and Other Assets

-----

We do not anticipate the sale of any material property, plant or equipment during the next 12 months. We do not anticipate the acquisition of any material property, plant or equipment during the next 12 months.

### Number of Employees

-----

From our inception through the period ended March 31, 2004, we have relied on the services of outside consultants for services and have one (1) employee. Our sole full time employee is our Chief Executive Officer, Michael K. Wilhelm. In order for us to attract and retain quality personnel, we anticipate we will have to offer competitive salaries to future employees. We anticipate that it may become desirable to add additional full and or part time employees to discharge certain critical functions during the next 12 months. This projected increase in personnel is dependent upon our ability to generate revenues and obtain sources of financing. There is no guarantee that we will be successful in raising the funds required or generating revenues sufficient to fund the projected increase

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

in the number of employees. As we continue to expand, we will incur additional cost for personnel.

### Trends, Risks and Uncertainties

-----

We have sought to identify what we believe to be the most significant risks to our business, but we cannot predict whether, or to what extent, any of such risks may be realized nor can we guarantee that we have identified all possible risks that might arise. Investors should carefully consider all of such risk factors before making an investment decision with respect to our Common Stock.

15

### RISK FACTORS

The actual results of the combined company may differ materially from those anticipated in these forward-looking statements. The Registrant and ImmuneRegen will operate as a combined company in a market environment that is difficult to predict and that involves significant risks and uncertainties, many of which will be beyond the combined company's control. Additional risks and uncertainties not presently known, or that are not currently believed to be important to you, if they materialize, also may adversely affect the combined company.

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

As March 31, 2004, our working capital totaled approximately \$(1,360,202). ImmuneRegen has incurred a substantial net loss for the period from its inception in October 2002 to March 31, 2004, and we are 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, ImmuneRegen will need to generate significant revenues to achieve profitability. If our revenues grow more slowly than we anticipate, or if its operating expenses exceed its expectations, we may experience reduced profitability.

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

Our independent certified public accountants have stated in their report included in Form 10-KSB that the Company has incurred a net loss and negative cash flows from operations of \$3,137,772 and \$1,167,342, respectively, for the period of inception from October 30, 2002 to March 31, 2004, 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 ImmuneRegen's ability to raise capital, its relationship with potential suppliers and customers, and have other unforeseen effects.

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.

ImmuneRegen has focused on product development and has not generated any revenue to date. We have incurred operating losses since our inception.

We currently have no product candidates for sale in the United States, and we

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

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 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.

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

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.

16

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 March 31, 2004, our cash and cash equivalents totaled approximately \$24,855. 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 March 31, 2004 was \$(1,360,202). 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.



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

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

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

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 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

17

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;

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

- o testing and surveillance to monitor our future products and their continued compliance with regulatory requirements;
- o submitting products for inspection and, if any inspection reveals that the product is not in compliance, prohibiting the sale of all products;
- o suspending manufacturing; or
- o withdrawing marketing clearance.

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

Even if human clinical trials of Homspira are initiated and successfully completed, the FDA may not approve Homspira 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 Homspira as "treatment" protocols. The FDA may not determine that Homspira meets all of the FDA's criteria for use of an investigational drug for treatment use. Even if Homspira is allowed for treatment use, third party payers may not provide reimbursement for the costs of treatment with Homspira. The FDA also may not consider Homspira 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.

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

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

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

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

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

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

- 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

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

drug candidate;

- o new communications from regulatory agencies about how to conduct these studies; or,
- o failure to raise additional funds.

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

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

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

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

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

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

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 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 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

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

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.

20

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 proprietary 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



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

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 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 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.

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

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

influence all matters submitted to our stockholders for approval, including the election

21

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 March 31, 2004.

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.

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

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

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.

### ITEM 3. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures.

The term "disclosure controls and procedures" refers to the controls and procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under Rules 13a-14 of the Securities Exchange Act of 1934 (the "Exchange Act") is recorded, processed,

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

summarized and reported within required time periods. As of the period covered by this quarterly report on form 10-QSB (the "Evaluation Date"), we carried

22

out an evaluation under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer of the effectiveness of our disclosure controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the Evaluation Date, such controls and procedures were effective in ensuring that required information will be disclosed on a timely basis in our periodic reports filed under the Exchange Act.

### (b) Changes in internal controls

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or 15d-15 under the Exchange Act that occurred during the quarter ended March 31, 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

23

## PART II - OTHER INFORMATION

### ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

#### (a) Exhibits

31.1 Certification of Chief Executive Officer pursuant to Securities Exchange Act Rule 13a-14(a).

31.2 Certification of Chief Financial Officer pursuant to Securities Exchange Act Rule 13a-14(a).

32 Certification pursuant to U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*

#### (b) Reports on Form 8-K

None.

23

\* This exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any filings.

### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant 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 Wilhelm

-----  
Michael Wilhelm  
President, Chief Executive Officer