

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

IR BIOSCIENCES HOLDINGS INC  
Form 10QSB/A  
July 20, 2005

FORM 10-QSB/A  
Amendment No. 1

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 September 30, 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

13-3301899

-----  
(State or other jurisdiction of incorporation or organization)

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

4021 N. 75th Street , Suite 201, Scottsdale, Arizona 85251

-----  
(Address of principal executive offices) Zip Code

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

-----  
(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  
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The number of shares outstanding of Registrant's common stock as of November 10, 2004 was 61,839,163.

IR BIOSCIENCES, INC. AND SUBSIDIARY

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### ITEM 1. FINANCIAL INFORMATION

IR BioSciences Holdings, Inc. and Subsidiary  
(A Development Stage Company)  
Condensed Consolidated Balance Sheet

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	September 30, 2004
	-----
Assets	
Current assets	
Prepaid services and other assets	\$    2,300
	-----
Total current assets	2,300
Licensed proprietary rights, net	7,552
Furniture and equipment, net	2,286
	-----
Total assets	\$    12,138
	=====
Liabilities and Stockholders' Deficit	
Current liabilities	
Cash overdraft	5,153
Current portion of notes payable, net of discount	1,044,365
Accounts payable and accrued liabilities	899,831
	-----
Total current liabilities	1,949,349
Long-term notes payable, net of discount	31,515
Commitments and Contingencies	
Stockholders' deficit Preferred stock, 0.001 par value:	
10,000,000 shares authorized, no shares issued and outstanding	--
Common stock, \$0.001 par value; 100,000,000 shares authorized; 29,621,776 shares issued and outstanding	29,621
Additional paid-in capital	4,555,194
Deferred compensation	(597,853)
Deficit Accumulated during the Development Stage	(5,955,688)
	-----
Total stockholder's deficit	(1,968,726)
	-----
Total liabilities and stockholders' deficit	\$    12,138
	=====

The accompanying notes are an integral part of these condensed consolidated financial statements.

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IR BioSciences Holdings, Inc. and Subsidiary

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(A Development Stage Company) Cumulative  
Condensed Consolidated Statements of Operations

	For the Three Months Ended September 30, 2004 -----	For the Three Months Ended September 30, 2003 -----	For the Nine Months Ended September 30, 2004 -----
Revenues	\$ --	\$ --	\$ --
Operating expenses:			
Selling, general and administrative expenses	1,041,152	297,587	3,546,641
Merger fees and costs	--	350,000	--
Financing cost	--	90,000	--
	-----	-----	-----
Total operating expenses	1,041,152	737,587	3,546,641
Operating loss	(1,041,152)	(737,587)	(3,546,641)
Other expense:			
Interest expense	(70,612)	(89,020)	(506,427)
	-----	-----	-----
Total other expense	(70,612)	(89,020)	(506,427)
Loss before income taxes	(1,111,764)	(826,607)	(4,053,068)
Provision for income taxes	--	--	--
	-----	-----	-----
Net Loss	\$ (1,111,764) =====	\$ (826,607) =====	\$ (4,053,068) =====
Net loss per share - basic and diluted	\$ (0.04) =====	\$ (0.04) =====	\$ (0.15) =====
Weighted average shares outstanding - basic and diluted	29,040,133 =====	23,379,818 =====	27,129,221 =====

The accompanying notes are in integral part of these condensed  
consolidated financial statements.

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IR BioSciences Holdings, Inc. and Subsidiary  
(A Development Stage Company)  
Condensed Consolidated Statements of Cash Flows

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	For the Nine Months Ended September 30, 2004 -----	For the Nine Months Ended September 30, 2003 -----	Cumulative From Inception (October 30, 2002) to September 30, 2004 -----
Cash flows from operating activities:			
Net loss	\$ (4,053,068)	\$ (1,218,323)	\$ (5,955,688)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash compensation	2,636,280	28,779	2,751,703
Interest expense	74,517	--	143,141
Amortization of discount on notes payable	406,360	60,582	708,662
Depreciation and amortization	12,454	9,470	25,216
Changes in operating assets and liabilities:			
Prepaid services and other assets	33,543	(49,043)	(2,299)
Accounts payable and accrued expenses	440,970	290,906	847,158
	-----	-----	-----
Net cash used in operating activities	(448,944)	(877,629)	(1,482,107)
Cash flows from investing activities:			
Acquisition of property and equipment	--	(3,304)	(3,304)
	-----	-----	-----
Net cash used in investing activities	--	(3,304)	(3,304)
Cash flows from financing activities:			
Proceeds from notes payable	576,057	795,000	1,777,057
Principal payments on notes payable	(174,000)	(200,000)	(424,000)
Proceeds from third parties for advances	--	265,000	96,001
Shares of stock sold for cash	31,200	65,000	31,200
Officer repayment of amounts paid on his behalf	--	--	19,880
Cash paid on behalf of officer	--	(19,880)	(19,880)
Cash paid on amount due to officer	--	(22,427)	--
	-----	-----	-----
Net cash provided by financing activities	433,257	882,693	1,480,258
Net increase in cash and cash equivalents	(15,687)	1,760	(5,153)
Cash and cash equivalents at beginning of period	10,534	32,155	--
	-----	-----	-----
Cash and cash equivalents at end of period	\$ (5,153)	\$ 33,915	\$ (5,153)
	=====	=====	=====
Cash paid during the period for:			
Interest	\$ 4,553	\$ 40,000	\$ 46,346
Taxes	\$ --	\$ --	\$ --

The accompanying notes are an integral part of these condensed

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consolidated financial statements.

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### Non-cash investing and financing activities:

In January 2004, the Company issued 800,000 shares (post-split) of common stock with a fair market value of \$800,000 to a consultant.

In February 2004, the Company issued 40,000 shares (post-split) of common stock with a fair market value of \$24,800 to a consultant.

In March 2004, the Company issued 1,051,600 shares (post-split) of common stock with a fair market value of \$420,640 to a consultant.

In March 2004, the Company issued 500,000 shares (post-split) of common stock with a fair market value of \$250,000 to a consultant.

In March 2004, the Company issued 67,800 shares (post-split) of common stock with a fair market value of \$10,800 to consultants.

In March 2004, the Company issued 45,800 shares (post-split) of common stock with a fair market value of \$29,132 to a vendor in satisfaction of accounts payable.

In April 2004, the Company issued 200,000 shares (post-split) of common stock with a fair market value of \$64,000 to its Chief Financial Officer in payment for services rendered.

In May 2004, the Company converted a Note Payable in the amount of \$35,000 into 350,000 shares (post-split) of common stock.

In May 2004, the Company issued 125,000 shares (post-split) of common stock with a fair market value of \$25,000 to a consultant.

In May 2004, the Company issued 500,000 shares (post-split) of common stock with a fair market value of \$500,000 to a consultant.

In July through September 2004, the Company issued 200,000 shares (post-split) of common stock with a fair market value of \$82,000 to a consultant.

In July 2004, the Company issued 250,000 shares (post-split) of common stock with a fair market value of \$25,000 to a consultant.

In August 2004, the Company issued 100,000 shares (post-split) of common stock with a fair market value of \$14,000 to a consultant.

In August 2004, the Company issued 200,000 shares (post-split) of common stock for conversion of a note payable of \$30,000.

In July through August 2004, the Company issued 300,000 shares (post-split) of common stock with a fair market value of \$36,000 to as interest on a note.

In September 2004, the Company issued 127,276 shares (post-split) of common stock with a fair market value of \$16,910 to a consultant.

The accompanying notes are an integral part of these condensed consolidated financial statements.

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IR BIOSCIENCES HOLDING, INC. AND SUBSIDIARY  
(A Development Stage Company)  
Consolidated Statement of Deficiency in Stockholders' Equity From date  
of inception (October 30, 2002) to June 30, 2004

(Unaudited)

	COMMON STOCK		AMOUNT PAID IN CAPITAL	DEFERRED COMPENSATION
	SHARES	AMOUNT		
Balance at October 30, 2002 (date)	--	\$ --	\$ --	\$ --
Shares of common stock issued at \$0.0006 per share to founders for license of proprietary right in December 2002 .....	16,612,276	16,612	(7,362)	--
Shares of common stock issued at \$0.0006 per share to founders for services rendered in December 2002 .....	1,405,310	1,405	(623)	--
Shares of common stock issued at \$0.1671 per share to consultants for services rendered in December 2002 .....	53,878	54	8,946	(9,000)
Sale of common stock for cash at \$0.1671 per share in December 2002 .....	185,578	186	30,815	--
Net loss for the period from inception (October 30, 2002) to December 31, 2002 .....	--	--	--	--
Balance at December 31, 2002.....	18,257,042	18,257	31,776	(9,000)
Shares granted to consultants at \$0.1392 per share for services rendered in January 2003 .....	98,776	99	13,651	--
Sale of shares of common stock for cash at \$0.1517 per share in January 2003 .....	329,552	330	49,670	--
Shares granted to consultants at \$0.1392 per share for services rendered in March 2003 .....	154,450	154	21,346	--
Conversion of notes payable to common stock at \$0.1392 per share in April 2003 .	1,436,736	1,437	198,563	--
Shares granted to consultants at \$0.1413 per share for services rendered in April 2003 .....	14,368	14	2,016	--
Sale of shares of common stock for cash at \$0.2784 per share in May 2003 .....	17,960	18	4,982	--
Sales of shares of common stock for cash at \$0.2784 per share in June 2003 .....	35,918	36	9,964	--
Conversion of notes payable to common stock at \$0.1392 per share in June 2003 .....	718,368	718	99,282	--

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Beneficial conversion feature associated with notes issued in June 2003 .....	--	--	60,560	--
Amortization of deferred compensation .....	--	--	--	9,000
Costs of GPN Merger in July 2003	2,368,130	2,368	(123,168)	--
Value of warrants issued with extended notes payable in October 2003 .....	--	--	189,937	--
Value of Company warrants issued in conjunction with fourth quarter notes payable issued October through December 2003	--	--	207,457	--

The accompanying notes are an integral part of these condensed consolidated financial statements.

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	COMMON STOCK		AMOUNT PAID	DEFERRED	A
	SHARES	AMOUNT	IN CAPITAL	COMPENSATION	
	-----	-----	-----	-----	-----
Value of warrants contributed by founders in conjunction with fourth quarter notes payable issued October through December 2003 .....	--	--	183,543	--	
Value of warrants issued for services in October through December 2003 .....	--	--	85,861	--	
Net loss for the year ended December 31, 2003 .....	--	--	--	--	
Balance at December 31, 2003 ..	23,431,300	23,431	1,035,441	--	
Shares granted at \$1.00 per share pursuant to the Senior Note Agreement in January 2004 .....	600,000	600	599,400	(600,000)	
Shares issued in January 2004 at \$1.00 per share to a consultant for services .....	800,000	800	799,200	(800,000)	
Shares issued in February 2004 to a consultant at \$0.62 per share for services .....	40,000	40	24,760	(24,800)	
Shares issued in March 2004 to a consultant at \$0.40 per share for services .....	1,051,600	1,052	419,588	(420,640)	
Shares issued in March 2004 to a consultant at \$0.50 per share for services .....	500,000	500	249,500	(250,000)	
Shares sold for cash in March 2004 at \$0.15 per share .....	8,000	8	1,192	--	
Shares issued in March 2004 at \$0.2857 per share to consultants for services .....	67,800	68	10,732	--	
Shares issued in March 2004 at					



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\$0.64 per share to consultants for services .....	45,800	45	29,267	--
Amortization of deferred compensation through March 2004	--	--	--	688,027
Shares to be issued to a consultant at \$0.41 per share for contracted services .....	--	--	--	(82,000)
Shares granted pursuant to the New Senior Note Agreement in April 2004 .....	600,000	600	149,400	(150,000)
Shares issued in April 2004 to officer at (0.32 per share for services .....	200,000	200	63,800	--
Conversion of Note Payable to common stock at \$0.10 per share in May 2004 .....	350,000	350	34,650	--
Beneficial Conversion Feature associated with note payable in May 2004 .....	--	--	52,500	--
Issuance of warrants to officers and founder in May 2004 for services .....	--	--	250,704	--
Shares to a consultant in May 2004 at \$0.20 per share as a due diligence fee .....	125,000	125	24,875	--
Shares issued to a consultant in May 2004 at \$1.00 per share for services .....	500,000	500	499,500	(500,000)
Beneficial Conversion Feature associated with notes payable issued in April, May, and June 2004 .....	--	--	20,938	--
Issuance of warrants to employees and consultants for services rendered in April through June 2004 .....	--	--	5,427	--
Amortization of deferred compensation through June 2004 .	--	--	--	952,069

The accompanying notes are an integral part of these condensed consolidated financial statements.

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	COMMON STOCK		AMOUNT PAID IN CAPITAL	DEFERRED COMPENSATION
	SHARES	AMOUNT		
Shares issued in July to a consultant at \$0.10 for services to be rendered through July 2005.....	250,000	250	24,750	(25,000)
Shares issued to a consultant in July and September at \$0.41 per share for services to be				

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rendered through April 2005.....	200,000	200	81,800	
Shares issued from July to September 2004 as interest on note payable.....	300,000	300	35,700	
Accrued deferred compensation in August 2004 to a consultant for 100,000 shares at \$0.10 per share, committed but unissued...	--	--	--	(10,000)
Shares issued in August 2004 at \$0.14 to a consultant for services to be performed through October 2004.....	100,000	100	13,900	(14,000)
Shares issued in August 2004 at \$0.125 per share for conversion of \$30,000 demand loan.....	200,000	200	29,800	--
Shares issued in August 2004 at \$0.16 per share to a consultant for services provided.....	125,000	125	19,875	--
Shares issued to a consultant in September at \$0.12 to \$0.22 for services rendered through September 2004	127,276	127	16,783	--
Issuance of warrants to employees and consultants for services through September, 2004			61,716	
Amortization of deferred compensation through September, 2004				638,491
Loss for the nine months ended September 30, 2004				
Balance at September 30, 2004...	29,621,776	\$ 29,621	\$ 4,555,194	\$ (597,853)
	=====	=====	=====	=====

The accompanying notes are an integral part of these condensed consolidated financial statements.

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IR BIOSCIENCES HOLDINGS, INC.  
(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

SEPTEMBER 30, 2004  
(Unaudited)

NOTE 1 - SUMMARY OF ACCOUNTING POLICIES

General  
-----

The accompanying unaudited condensed financial statements have been prepared in accordance with the instructions to Form 10-QSB, and therefore, do not include all the information necessary for a fair presentation of financial position, results of operations and cash flows in conformity with accounting principles generally accepted in the United States of America for a complete set of financial statements.

In the opinion of management, all adjustments (consisting of normal recurring

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accruals) considered necessary for a fair presentation have been included. The results from operations for the three-month and nine-month periods ended September 30, 2004 are not necessarily indicative of the results that may be expected for the year ended December 31, 2004. The unaudited condensed consolidated financial statements should be read in conjunction with the December 31, 2003 financial statements and footnotes thereto included in the Company's Securities and Exchange Commission Form 10-KSB.

### Business and Basis of Presentation

-----

ImmuneRegen BioSciences, Inc. ("Company" or "ImmuneRegen") is currently a development stage company under the provisions of Statement of Financial Accounting Standards ("SFAS") No. 7. The Company was incorporated under the laws of the State of Delaware on October 30, 2002, and has a December 31 year-end. ImmuneRegen is a biotechnology company and plans to develop and market applications utilizing modified substance P, a naturally occurring immunomodulator.

### Reclassification

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Certain reclassifications have been made to conform to prior periods' data to the current presentation. These reclassifications had no effect on reported losses.

### Stock Based Compensation

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In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation-Transition and Disclosure-an amendment of SFAS 123." This statement amends SFAS No. 123, "Accounting for Stock-Based Compensation," to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this statement amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The Company has chosen to continue to account for stock-based compensation using the intrinsic value method prescribed in APB Opinion No. 25 and related interpretations. Accordingly, compensation expense for stock options is measured as the excess, if any, of the fair market value of the Company's stock at the date of the grant over the exercise price of the related option. The Company has adopted the annual disclosure provisions of SFAS No. 148 in its financial reports for the year ended December 31, 2002 and for the subsequent periods.

### Reverse acquisition

-----

ImmuneRegen BioSciences, Inc., a private corporation, was formed on October 30, 2002 according to the laws of Delaware. On July 2, 2003, GPN Network, Inc. ("Registrant") and ImmuneRegen entered into and consummated an Agreement and Plan of Merger (the "Merger"). In accordance with the Merger, on July 2, 2003, the Registrant, through its wholly-owned subsidiary, GPN Acquisition Corporation, a Delaware corporation ("Merger Sub"), acquired ImmuneRegen in exchange for 21,063,170 shares (post split) of the Registrant's 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.

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The stockholders of ImmuneRegen (aggregating approximately 40) owned approximately 90% of the Registrant's common stock outstanding immediately after the effective time of the Merger (excluding any additional shares issuable upon outstanding options, warrants and other securities convertible into our common stock).

Under Delaware law, the Registrant did not need to obtain the approval of its stockholders to consummate the Merger, as the constituent corporations in the merger were Merger Sub and ImmuneRegen, each of which are business entities incorporated under the laws of Delaware. The Registrant is not a constituent corporation in the Merger.

For accounting purposes, this transaction was accounted for as a reverse merger, since the stockholders of ImmuneRegen own a majority of the issued and outstanding shares of common stock of the Registrant, and the directors and executive officers of ImmuneRegen became the directors and executive officers of the Registrant. No agreements exist among present or former controlling stockholders of the Registrant or present or former members of ImmuneRegen with respect to the election of the members of our board of directors, and to the Registrant's knowledge, no other agreements exist which might result in a change of control of the Registrant.

### Going Concern

-----

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, which contemplate continuation of the Company as a going concern. However, the Company has no established source of revenue. This matter raises substantial doubt about the Company's ability to continue as a going concern. These financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts, or amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Management plans to take the following steps that it believes will be sufficient to provide the Company with the ability to continue in existence: Management intends to continue to raise additional financing through private debt or equity financing or other means and interests that it deems necessary, with a view to moving forward and sustaining a prolonged growth in its strategy phases. The Company believes that its status as a publicly traded company will improve its chances of raising funds through either equity or debt financings.

### Interim Financial Statements

-----

The accompanying balance sheet as of September 30, 2004, the statements of operations for the three months and nine months ended September 30, 2004 and 2003, and for the period from inception to September 30, 2004, and the statements of cash flows for the nine months ended September, 2004 and 2003, and from the period of inception (October 30, 2002) to September 30, 2004 are unaudited. These unaudited interim financial statements include all adjustments (consisting of normal recurring accruals), which, in the opinion of management, are necessary for a fair presentation of the results of operations for the periods presented. Interim results are not necessarily indicative of the results to be expected for a full year.

### Use of Estimates

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The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make

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estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reported periods. Actual results could materially differ from those estimates.

### Long-Lived Assets

-----

The Company accounts for its long-lived assets under the provision of Statements of Financial Accounting Standards No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets To Be Disposed Of." The Company's long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Events relating to recoverability may include significant unfavorable changes in business conditions, recurring losses, or a forecasted

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inability to achieve break-even operating results over an extended period. The Company evaluates the recoverability of long-lived assets based upon forecasted undercounted cash flows. Should an impairment in value be indicated, the carrying value of intangible assets will be adjusted, based on estimates of future discounted cash flows resulting from the use and ultimate disposition of the asset.

### Prepaid Services

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Prepaid services consist of outside services that the Company has paid for in advance. At September 30, 2004 this amount was \$2,300 consisting of an employee advance.

### Licensed Proprietary Rights

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The Company has licensed from its founders certain proprietary rights which the Company intends to utilize in the execution of its business plan. These proprietary rights are being amortized over the term of the license agreement, or ten years. The amount amortized during the three months and nine months ended September 30, 2004 was \$232 and \$696, respectively.

### Furniture and Equipment

-----

Furniture and equipment are valued at cost. Depreciation and amortization are provided over the estimated useful lives up to seven years using the straight-line method. The estimated service lives of property and equipment are as follows:

Computer equipment	3 years
Furniture	7 years

The amount depreciated for the three months and nine months ended September 30, 2004 were \$170 and \$510 respectively. The amounts depreciated for the three months and nine months ended September, 2003 were \$170 and \$340 respectively, The amount depreciated from the date of inception (October 30, 2002) through

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September 30, 2004 was \$1,019 .

### NOTE 3 - NEW ACCOUNTING PRONOUNCEMENTS

In January 2003, the FASB issued interpretation No. 46, Consolidation of Variable Interest Entities (FIN 46), as revised December 2003. This interpretation of Accounting Research Bulletin No. 51, Consolidated Financial Statements, addresses consolidation by business enterprises of variable interest entities (VIEs) that either: (1) do not have sufficient equity investment at risk to permit the entity to finance its activities without additional subordinated financial support, or (2) the equity investors lack an essential characteristic of a controlling financial interest. This interpretation applies immediately to VIEs created after January 31, 2003. It applies in the first fiscal year or interim period beginning after June 15, 2003, to VIEs in which an enterprise holds a variable interest that it acquired before February 1, 2003. The application of FIN 46 did not have a material effect on our consolidated financial statements.

### NOTE 4 - RELATED PARTY TRANSACTIONS

#### Founder's Consulting Fees

-----

During the three months and nine months ended September 30, 2004, the Company accrued \$30,000 and \$90,000, respectively, in consulting fees payable to two of the Company's founders.

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#### In-One Contract

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The Company has entered into a series of contracts for marketing, website development, and website hosting with In-One Advertising ("In-One"), a company run by the spouse of the Company's CEO. Pursuant to these contracts, during the nine months ended September 30, 2004, the Company issues 91,600 shares (post-split) of its common stock to with a value of \$29,312 to In-One.

#### Office Lease

-----

The Company subleases its office space from Foresight Capital Partners, a company controlled by the Company's CEO. The rent cost is passed through to the Company at the same rental rate that Foresight Capital Partners is charged by the facility's primary landlord. Rent expense amounted to \$7,196 and \$24,332, respectively, for the three and nine month periods ended September 30, 2004.

#### Stratum Consulting Agreement

-----

On April 1, 2004, the Company entered into a consulting agreement with Stratum Consulting Group, Inc. ("Stratum", "The Stratum Agreement") a company controlled by the Company's Secretary. The Stratum Agreement has a term of twelve months, and calls for Stratum to provide financial consulting to the Company in return for the following: 200,000 shares (post-split) of the Company's common stock upon execution of the agreement, and the number of shares of the Company's

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common stock equal to \$2,500 per month for the term of the agreement. The Stratum agreement also calls for a cash fee of an additional \$2,500 per month.

During the three months ended September 30, 2004, the Company issued 127,776 shares (post reverse-split) of common stock to Stratum, and accrued \$7,500 in cash fees. At September 30, 2004, the Company has accrued a total of \$12,500 in cash fees due to Stratum.

### NOTE 3 - DEBT

At September 30, 2004, the Company had the following debt outstanding:

	Principal	Discount	Net Book Value
<b>Current:</b>			
Amended Secured Convertible Promissory Notes	\$ 245,000	\$ --	\$ 245,000
Fourth Quarter Secured Convertible Promissory Notes	337,000	--	337,000
Senior Secured Promissory Note	154,500	--	154,500
Other Notes Payable	310,653	(2,788)	307,865
	\$1,047,153	\$ (2,788)	\$ 1,044,365
	=====	=====	=====
<b>Long term:</b>			
Other Notes Payable	\$ 35,000	\$ (3,485)	\$ 31,515
	=====	=====	=====

#### Amended Secured Convertible Promissory Notes

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At September 30, 2004, the Company had outstanding five Amended Secured Convertible Promissory Notes in the aggregate amount of \$245,000. Interest accrued for the three and nine months ended September 30, 2004 was \$4,940 and \$14,576, respectively. Total accrued interest due on the Amended Notes at September 30, 2004 was \$18,908. At September 30, 2004, these notes were in default as they had not been paid at their maturity date. All of the Amended Secured Convertible Promissory Notes were either paid or converted to common stock in October and November 2004.

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#### Fourth Quarter Secured Convertible Promissory Notes

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At September 30, 2004, the Company had outstanding nine Amended Secured Convertible Promissory Notes in the aggregate amount of \$337,000. Interest accrued for the three and nine months ended September 30, 2004 was \$6,795 and \$21,622, respectively. Total accrued interest due on the Fourth Quarter Notes at September 30, 2004 was \$28,330. At September 30, 2004, eight of the nine Fourth Quarter Notes were in default as they had not been paid at their maturity date. All of the Fourth Quarter Secured Convertible Promissory Notes were either paid or converted to common stock in October and November 2004.

#### Senior Secured Promissory Notes

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At September 30, 2004, the Company had outstanding one Senior Secured Promissory Note in the amount of \$154,500 (the "New Senior Note"). The New Senior Note bears interest at the rate of 12% per annum and has a term of 90 days. Interest accrued on the New Senior Secured Note for the three and nine months period ending September 30, 2004 was \$4,672 and \$7,924, respectively. The New Senior Note is senior secured indebtedness of the Company and is secured by certain collateral. As additional incentive to enter into the New Senior Note, the Company provided 600,000 shares (post-split) of the Company's common stock valued at \$150,000. During the three months ended September 30, 2004, the New Senior Note was extended to October 11, 2004. As compensation for extending the due date of this note, the Company issued 300,000 shares of its common stock with a fair value of \$36,000. The New Senior Note was paid in November 2004.

### Other Notes Payable

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At June 30, 2004, the Company had outstanding eight other notes payable (the "Other Notes") in the aggregate principal amount of \$211,581, net of discount associated with beneficial conversion features of \$13,411. These notes bear interest at rates ranging from 6% to 12% per annum. During the three months ended September 30, 2004, the Company entered into five new note agreements in the aggregate amount of \$133,100 bearing interest at rates ranging from 8% to 12% per annum, and capitalized \$972 of interest on one of the notes. At September 30, 2004 the Company had outstanding a total of thirteen Other Notes in the aggregate amount of \$345,653. Eleven of these in the aggregate amount of \$307,865 (net of discount of \$2,788) are due less than one year from September 30, 2004; two of these in the aggregate amount of \$31,515 (net of discount of \$3,485) are due in April and May 2006. Accrued interest on the Other Notes amounted to \$5,725 for the \$9,430 for the three and nine months ended September 30, 2004, respectively. Three notes in the aggregate amount of \$84,081 were in default at September 30, 2004 as they have not been paid by their due dates. Eight notes in the aggregate amount of \$225,600 were either paid or converted to common stock in October and November 2004.

### NOTE 4 - EQUITY

#### Stock Split

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On April 6, 2004, the Company effected a two-for-one forward split of its common stock. The number of shares of common stock outstanding immediately prior to the reverse split was 13,272,250; the number of shares of common stock outstanding immediately after the reverse split was 26,544,500. The accompanying financial statements reflect the effect of this stock split.

#### Common Stock

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In January 2004, the Company entered into the Senior Note Agreement (see Note 3). Pursuant to this agreement, the Company issued to the lender 600,000 shares (post-split) of the Company's common stock valued at \$600,000. This amount was charged to deferred compensation and additional paid-in capital, and is being amortized over the term of the 90 day term of the Senior Note. During the three months and six months ended June 30, 2004, \$106,667 and \$600,000 of this amount, respectively, had been charged to non-cash compensation.

In January 2004, the Company issued 800,000 shares (post-split) of common stock with a fair market value of \$800,000 to a consultant in exchange for services to be provided through January 2005. This amount was charged to deferred compensation and additional paid-in capital, and is being amortized over the



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term of the 360 day Agreement. During the three months and six months ended June 30, 2004, \$204,444 and \$362,222 of this amount, respectively, had been charged to non-cash compensation.

In February 2004, the Company issued 40,000 shares of common stock with a fair market value of \$24,800 to a consultant in exchange for services to be provided through August 2004. This amount was charged to deferred compensation and additional paid-in capital, and is being amortized over the term of the 180 day Agreement. During the three and six months ended June 30, 2004, \$12,676 and \$19,564 of this amount, respectively, had been charged to non-cash compensation.

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In March 2004, the Company issued 1,051,600 shares (post-split) of common stock with a fair market value of \$420,640 to a consultant in exchange for services to be provided through March 2005. This amount was charged to deferred compensation and additional paid-in capital, and is being amortized over the term of the 360 day Agreement. During the three and six months ended June 30, 2004, \$107,497 and \$125,024 of this amount, respectively, been charged to non-cash compensation.

In March 2004, the Company issued 500,000 shares (post-split) of common stock with a fair market value of \$250,000 to a consultant in exchange for services to be provided through September 2004. This amount was charged to deferred compensation and additional paid-in capital, and is being amortized over the term of the 180 day Agreement. During the three and six months ended June 30, 2004, \$127,778 and \$140,278 of this amount, respectively, had been charged to non-cash compensation.

In March 2004, the Company issued 8,000 shares (post-split) of common stock with a fair market value of \$1,200 for cash.

In March 2004, the Company issued 67,800 shares (post-split) of common stock with a fair market value of \$10,800 to various consultants in exchange for services rendered. This amount was charged to non-cash compensation.

In March 2004, the Company issued 45,800 shares (post-split) of stock with a market value of \$29,312 to InOne as payment for outstanding payables.

In April 2004, the Company entered into the New Senior Note Agreement (see Note 3). Pursuant to this agreement, the Company issued to the lender 600,000 shares (post-split) of the Company's common stock valued at \$150,000. This amount was charged to deferred compensation and additional paid-in capital, and is being amortized over the term of the 90 day term of the New Senior Note. During the three months and six months ended June 30, 2004, \$103,846 of this amount had been charged to non-cash compensation.

In April 2004, the Company issued 200,000 shares (post-split) of stock with a market value of \$64,000 to its Chief Financial Officer for services rendered. This amount was charged to non-cash compensation.

In May 2004, the Company issued 350,000 shares (post-split) of stock with a market value of \$87,500 via conversion of a note payable in the amount of \$35,000. The Company recorded a charge to interest expense for the beneficial conversion feature of this transaction in the amount of \$52,500.

In May 2004, the Company issued 125,000 shares (post-split) of stock with a market value of \$25,000 to a consultant as a due diligence fee. This amount was charged to non-cash compensation.

In May 2004, the Company issued 500,000 shares (post-split) of stock with a market value of \$500,000 to a consultant for services to be rendered through

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December 2004. This value was determined as of the date the consulting agreement was signed, which was in December 2003. This amount was charged to deferred compensation and additional paid-in capital, and is being amortized over the term of the agreement. During the three and six months ended June 30, 2004, \$268,493 of this amount has been charged to non-cash compensation.

In July 2004, the Company issued 250,000 shares (post-split) of stock with a market value of \$25,000 to a consultant for services to be rendered through July 2005. This amount was charged to deferred compensation.

In July and September 2004, the Company issued 200,000 shares of stock with a market value of \$82,000 to a consultant for services to be rendered through April 2005. This amount was charged to deferred compensation at the time the contract with this consultant was signed in April 2005.

In July, August, and September 2004, the Company issued 300,000 shares of stock with a market value of \$36,000 to a lender as consideration for extending the due date of a note payable. This amount was charged to interest expense.

In August 2004, the Company committed to issue 100,000 shares of common stock to a consultant for services rendered through July 2005. These shares are to be issued in October 2005. The Company charged the \$10,000 fair value of these shares to deferred compensation.

In August 2004, the Company issued 100,000 shares of common stock at a fair value of \$14,000 to a consultant for services to be rendered through October 2004. The Company charged this amount to deferred compensation.

In August 2004, the Company issued 200,000 shares of common stock for conversion of a note payable in the amount of \$30,000.

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In August 2004, the Company issued 125,000 shares of common stock at a fair value of \$20,000 to a consultant for services provided.

In September 2004, the Company issued 127,276 shares of common stock at a fair value of \$16,910 to a consultant for services provided through September 2004.

Except as otherwise indicated above, all valuations of the above shares are based on the stock price at the date of issue, which did not differ materially from the value of the services that were rendered by the consultants under the contracts.

### NOTE 5 - SUBSEQUENT EVENTS

In October 2004, Company completed the private placement (the "Private Placement") of 19,600,000 shares of its common stock at a price of \$0.125 per share for gross proceeds of \$2,450,000. The Company also converted approximately \$837,893 in notes payable and \$157,218 in vendor payables at the same terms as the Private Placement into 6,703,151 and 1,257,746 shares of common stock, respectively. Pursuant to the terms of the Private Placement, the Company also issued five-year warrants to purchase approximately 13,900,449 shares of the Company's common stock at a price of \$0.50.

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

Special note regarding forward-looking statements

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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

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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 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.

Our initial areas of focus will be in continuing development of several applications for use in improving pulmonary function and stimulating the immune

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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 Homspira compound as a treatment for lung injury caused by acute respiratory disease syndrome ("ARDS").

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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 Homspira 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.

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 Homspira 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 Homspira 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 SEPTEMBER 30, 2004

Revenue  
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We are in the development stage and have no revenue.

Sales, general, and administrative expenses  
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Sales, general, and administrative expenses ("SG&A") were \$1,041,162 for the

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three months ended September 30, 2004, an increase of \$743,565 or approximately 250% compared to SG&A of \$297,587 during the three months ended September 30, 2003. For the three months ended September 30, 2004, this amount consisted primarily of non-cash compensation issued to consultants of \$746,259, legal and accounting fees of \$63,366, other consulting fees of \$56,550, officer wages of \$43,750, contract labor of \$24,244, and research and development expenses of \$22,709. The increase was due primarily to an increase in the value of non-cash compensation, which was \$0 during the three months ended September 30, 2004.

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

### Interest expense

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Interest expense was \$70,612 for the three months ended September 30, 2004, a decrease of \$18,408 or approximately 21% compared to interest expense of \$89,020 for the three months ended September 30, 2003. In the quarter ended September 30, 2004, interest expense consisted of stock issued for interest and loan extension charges of \$36,000, interest accrued on notes payable of \$22,930, and amortization of discount on notes payable of \$11,682. Interest decreased from the comparable period of the prior year due to amortization of the beneficial conversion features of notes payable during the three months ended September 30, 2003.

The Company expects interest expense to decrease during the coming twelve months because most of the Company's outstanding debt was converted to equity in November 2004.

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### Net loss

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For the reasons above, the net loss for the three months ended September 30, 2004 was \$1,111,764, an increase of \$285,157 or 34.5% compared to a net loss of \$826,607 for the three months ended September 30, 2003.

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

## RESULTS OF OPERATIONS - NINE MONTHS ENDED SEPTEMBER 30, 2004

### Revenue

-----

We are in the development stage and have no revenue.

### Selling, General and Administrative Expenses

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SG&A expenses were \$3,546,641 for the nine months ended September 30, 2004, an increase of \$2,879,980 or approximately 432% compared to SG&A of \$666,661 for the nine months ended September 30, 2003. For the 2004 period, this amount consists primarily of non-cash compensation of \$2,600,818, legal and accounting fees of \$249,077, officer wages of \$131,350, consulting fees of \$121,550,

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research and development costs of \$84,519, and contract labor of \$65,747. The increase was due primarily to an increase in the value of non-cash compensation, which was \$0 during the nine months ended September 30, 2004.

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

### Interest expense

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Interest expense was \$506,427 for the nine months ended September 30, 2004, an increase of \$394,765 or approximately 354% compared to interest expense of \$111,662 for the nine months ended September 30, 2003. For the nine months ended September 30, 2004, interest expense consists of amortization of the discount on notes payable of \$412,815, and interest on notes payable of \$57,612, and stock issued for interest and loan extension charges of \$36,000.

The Company expects interest expense to decrease during the coming twelve months because most of the Company's outstanding debt was converted to equity in November 2004.

### Net loss

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For the reasons above, the net loss for the nine months ended September 30, 2004 was \$4,053,068, an increase of \$2,834,745 or approximately 35% compared to a net loss of \$1,218,323 for the nine months ended September 30, 2003.

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

### LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2004, we had current assets of \$2,300 consisting prepaid services of \$2,300. Also at September 30, 2004, we had current liabilities of \$1,949,349 consisting of a cash overdraft of \$5,153, notes payable net of discount of \$1,044,365 and accounts payable and accrued liabilities of \$899,831. This results in negative working capital of (\$1,947,049). During the nine months ended September 30, 2004, the Company used cash in operating activities of (\$448,944). From the date of inception (October 30, 2002) to September 30, 2004, the Company has had a net loss of (\$5,955,688) and has used cash of (\$1,482,107) in operating activities.

The Company currently has no revenue. There is no guarantee that our business model will be successful, or that we will be able to generate sufficient revenue to fund future operations. As a result, we expect our operations to continue to use net cash, and that we will be required to seek additional debt or equity financings during the coming quarters. Since Inception, the Company has financed its operations through debt and equity financing. While we have raised capital to meet our working capital and financing needs in the past, additional financing is required in order to meet our current and projected cash flow deficits from operations and development of our product line. In October 2004, the Company completed the private placement of its common stock for the gross amount of \$2,465,000. It is expected that in order to implement its business

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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

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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

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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

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From our inception through the period ended September 30, 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 in the number of employees. As we continue to expand, we will incur additional cost for personnel.

### Trends, Risks and Uncertainties

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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.

### 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

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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.

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

ImmuneRegen has incurred a substantial net loss for the period from its inception in October 2002 to September 30, 2004, and we are currently experiencing negative cash flow. ImmuneRegen expects 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 ImmuneRegen's revenues grow more slowly than it anticipates, or if its operating expenses exceed its expectations, ImmuneRegen may experience reduced profitability.

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

ImmuneRegen's 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 \$5,955,688 and \$1,482,107, respectively, for the period of inception of October 30, 2002 to September 30, 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 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



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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.

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

Our quarterly operating results may fluctuate significantly in the future as a result of a variety of factors, many of which are outside our control. These factors include: the level of demand for Homspera and any other products; our ability to attract and retain personnel with the necessary strategic, technical and creative skills required for effective operations; the amount and timing of expenditures by customers; the amount and timing of capital expenditures and other costs relating to the expansion of our operations; government regulation and legal developments regarding the use of Homspera; and general economic conditions. As a strategic response to changes in the competitive environment, we may from time to time make certain pricing, service, technology or marketing decisions that could have a material adverse effect on our quarterly results. Due to all of these factors, our operating results may fall below the expectations of securities analysts, stockholders and investors in any future quarter.

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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.

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

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

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 September 30, 2004, our cash and cash equivalents totaled approximately \$(2,853) in deficit. 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 September 30, 2004 was \$(1,947,049). 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.

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

All our potential applications are derived from the use of Homspira. In addition, we expect to utilize Homspira in the development of any future products we market. If these current or future products are found to be unsafe

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or ineffective due to the use of Homspera, we may have to modify or cease production of the products. As all of our applications utilize or will utilize Homspera, any findings that Homspera is unsafe or ineffective would severely harm our business operations, since all of our primary revenue sources would be negatively affected by such findings.

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

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

Our therapies and technologies utilizing Homspera 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 WE MAY NOT BE ABLE TO SUCCESSFULLY COMMERCIALIZE RADILEX.

We do not believe any drug has ever been approved and commercialized for the treatment of severe acute radiation injury. In addition, the incidence of large-scale exposure to nuclear or radiological events has been low. Accordingly, even if Radilex, our 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

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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.

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

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

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

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

A marketed product is subject to continual FDA review. Later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market, as well as possible civil or criminal

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sanctions. The FDA could withdraw a previously approved product from the market upon receipt of newly discovered information, including a failure to comply with regulatory requirements, the occurrence of unanticipated problems with products following approval, or other reasons, which could adversely affect our operating results.

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

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

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

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

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

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

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

- 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;

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

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

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

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

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

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

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- 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,
- 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.

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

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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 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.

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

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

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

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

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

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

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



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liability claim could hurt our financial performance. Even if we avoid liability exposure, significant costs could be incurred that could hurt our financial performance.

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

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

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

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

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

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

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

We own or have obtained a license to 4 issued U.S. and foreign patents and 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

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technologies, products and processes.

Our long-term success largely depends on our ability to market technologically competitive processes and products. If we fail to obtain or maintain these protections we may not be able to prevent third parties from using our proprietary rights. Our currently pending or future patent applications may not result in issued patents. In the United States, patent applications are confidential until patent applications are published or the patent is issued, and because third parties may have filed patent applications for technology covered by our pending patent applications without us being aware of those applications, our patent applications may not have priority over any patent applications of others. In addition, our issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products or provide us with any competitive advantage. If a third party initiates litigation regarding our patents, and is successful, a court could revoke our patents or limit the scope of coverage for those patents. Legal standards relating to the validity of patents covering pharmaceutical and biotechnology inventions and the scope of claims made under such patents are still developing. In some of the countries in which we intend to market our products, pharmaceuticals are either not patentable or have only recently become patentable. Past enforcement of intellectual property rights in many of these countries has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries may be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions.

The U.S. Patent and Trademark Office, commonly referred to as the USPTO, and the courts have not consistently treated the breadth of claims allowed in biotechnology patents. If the USPTO or the courts begin to allow broader claims, the incidence and cost of patent interference proceedings and the risk of infringement litigation will likely increase. On the other hand, if the USPTO or the courts begin to allow narrower claims, the value of our proprietary rights may be limited. Any changes in, or unexpected interpretations of the patent laws may adversely affect our ability to enforce our patent position.

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

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

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

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

The patent positions of biotechnology and pharmaceutical companies are often highly uncertain and involve complex legal and factual questions. Therefore, the breadth of claims allowed in biotechnology and pharmaceutical patents cannot be

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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

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

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

We may be required to incur significant costs to comply with current or future environmental laws and regulations. Although we do not currently manufacture commercial quantities of our proposed products, we do produce limited quantities of these products for our clinical trials. Our research and development and manufacturing processes involve the controlled storage, use and disposal of hazardous materials, biological hazardous materials and radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and some waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, the risk of contamination or injury from these materials cannot

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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

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Company Accounting Oversight Board and the NASD OTC Bulletin Board, have recently issued new requirements and regulations and are currently developing additional regulations and requirements in response to recent laws enacted by Congress, most notably the Sarbanes-Oxley Act of 2002. As certain rules are not yet finalized, we do not know the level of resources we will have to commit in order to be in compliance. Our compliance with current and proposed rules is likely to require the commitment of significant financial and managerial resources. As a result, our management's attention might be diverted from other business concerns, which could negatively affect our business.

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

Our officers, directors and principal stockholders, and their affiliates, in the aggregate, own over a majority of the outstanding shares of our common stock. As a result, such persons, acting together, have the ability to substantially influence all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets, and to control our management and affairs. Accordingly, such concentration of ownership may have the effect of delaying, deferring or preventing a change in discouraging a potential acquirer 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;

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- 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 September 30, 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.

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.

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

Our common stock is considered to be a "penny stock" since it meets one or more of the definitions in Rules 15g-2 through 15g-6 promulgated under Section 15(g) of the Securities Exchange Act of 1934, as amended. Section 15(g) of the Securities Exchange Act of 1934, as amended, and Rule 15g-2 promulgated thereunder by the SEC require broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document before effecting any transaction in a penny stock for the investor's account.

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Compliance with this and other requirements may make it more difficult for holders of our common stock to resell their shares to third parties or to otherwise dispose of them in the market or otherwise.

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

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, 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 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.

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### (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.

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## PART II - OTHER INFORMATION

### Item 1. Legal Proceedings

We are not a party to any material legal proceedings and there are no material legal proceedings pending with respect to our property. We are not aware of any legal proceedings contemplated by any governmental authorities involving either of us or our property. None of our directors, officers or affiliates is an adverse party in any legal proceedings involving us or our subsidiaries, or has an interest in any proceeding which is adverse to us or our subsidiaries.

### Item 2. Changes in Securities and Use of Proceeds

(a) None.

(b) None.

(c) During the three months ended September 30, 2004, we issued a total of 1,302,276 shares of our Common Stock to consultants and lenders for their marketing, investor relations and advisory services and as interest and loan extension fees. 145,000 of these shares are registered with Form S-8 of the Securities and Exchange Commission, and 1,157,276 of these shares are considered exempt from registration by reason of the Section 4(2) of the Securities Act of 1933.

(d) None.

### Item 3. Defaults Upon Senior Securities None.

### Item 4: Submission of Matters to a Vote of Securities Holders None.

### Item 5: Other Information None.

### 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).

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

32.2\* Certification of Chief Financial Officer 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

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None.

\* 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.

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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 July 20, 2005.

IR BioSciences Holdings, Inc.

By:

/s/ Michael Wilhelm

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Michael Wilhelm  
President, Chief Executive Officer

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