

Edgar Filing: IR BIOSCIENCES HOLDINGS INC - Form 10QSB

IR BIOSCIENCES HOLDINGS INC  
Form 10QSB  
November 22, 2004

FORM 10-QSB

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: (408) 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       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  
(A Development Stage Company) Cumulative

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## 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 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	--
Beneficial conversion feature				

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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
	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 \$0.64 per share to consultants				



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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 rendered through April 2005.....	200,000	200	81,800	

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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 accruals) considered necessary for a fair presentation have been included. The

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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

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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 estimates and assumptions that affect the reported amounts of assets and

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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.

### 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

-----

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.

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### Furniture and Equipment

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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 amounts 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 June 30, 2004 was \$1,019.

### NOTE 2 - RELATED PARTY TRANSACTIONS

#### Founder's Consulting Fees

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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.

#### 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

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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 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
Current:	-----	-----	-----
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
	=====	=====	=====
 Long term:			
Other Notes Payable	\$ 35,000	\$ (3,485)	\$ 31,515
	=====	=====	=====

### Amended Secured Convertible Promissory Notes

-----

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.

Fourth Quarter Secured Convertible Promissory Notes  
-----

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.

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### 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 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.



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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 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

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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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Some of the statements under "Risk Factors," "Business" and elsewhere in this Quarterly Report on Form 10-Q constitute forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among other things, those described under "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q.

In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expects," "plans," "intends," "anticipates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of such terms or other comparable terminology.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity, performance, or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of such statements. We are under no duty to update any of the forward-looking statements 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

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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 system. These applications have been derived from research studies and positive results from laboratory tests conducted by management over the past nine years.

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

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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 Homspera to those in need of it.

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

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

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We expect that our products will use an inhaler (puffer) device to deliver Homspera to the user. To develop, manufacture and test an inhaler device we hope to partner with a drug development and chemical services company that offers services ranging from pre-clinical and toxicology studies to clinical trial support and manufacturing services. We believe that such a partnership may enable us to decrease the time-to-market for our products and to increase our productivity.

### RESULTS OF OPERATIONS - THREE MONTHS ENDED 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 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

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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

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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, 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

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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.

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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 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. 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

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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 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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IMMUNEREGEN HAS AN ACCUMULATED DEFICIT, IS 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 is 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.

THE REGISTRANT WILL BE REQUIRED TO RAISE ADDITIONAL CAPITAL TO FUND IMMUNEREGEN'S OPERATIONS. IF IMMUNEREGEN CANNOT RAISE NEEDED ADDITIONAL CAPITAL IN THE FUTURE, IT WILL BE REQUIRED TO CEASE OPERATIONS.

ImmuneRegen requires substantial working capital to fund its operations. Since it does not expect to generate significant revenues in the foreseeable future, in order to fund operations, ImmuneRegen will be completely dependent on additional debt and equity financing arrangements. There is no assurance that any financing will be sufficient to fund its 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

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available or that, if available, can be obtained on terms favorable to ImmuneRegen. If ImmuneRegen is unable to raise needed funds on acceptable terms, ImmuneRegen will not be able to develop or enhance its products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require the Registrant to take drastic steps such as reducing ImmuneRegen's level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, ImmuneRegen will not be able to continue operations.

IMMUNEREGEN'S LIMITED OPERATING HISTORY MAKES IT DIFFICULT TO EVALUATE THE SUCCESS OF ITS BUSINESS MODEL AND THE EFFECTIVENESS OF ITS MANAGEMENT. IF IMMUNEREGEN'S PLAN IS NOT SUCCESSFUL, OR MANAGEMENT IS NOT EFFECTIVE, THE VALUE OF THE REGISTRANT'S COMMON STOCK MAY DECLINE.

ImmuneRegen was founded in October 2002. As a result, ImmuneRegen has a limited operating history on which you can base your evaluation of its business and prospects. ImmuneRegen's business and prospects must be considered in light of the risks and uncertainties frequently encountered by companies in their early stages of development. These risks and uncertainties include the following:

- o ImmuneRegen's ability to raise additional funding and the amounts raised, if any;
- o The time and costs involved in obtaining regulatory approvals;
- o Continued scientific progress in ImmuneRegen's research and development programs;
- o The scope and results of preclinical studies and clinical trials;
- o The costs involved in filing, prosecuting and enforcing patent claims;
- o Competing technological and market developments;
- o Effective commercialization activities and arrangements;
- o The costs of defending against and settling lawsuits; and
- o Other factors not within the combined company's control or known to it.

The combined company cannot be sure that it will be successful in meeting these challenges and addressing these risks and uncertainties. If we are unable to do so, ImmuneRegen's business will not be successful.

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IMMUNEREGEN'S FAILURE TO SUCCESSFULLY DEVELOP AND COMMERCIALIZE PRODUCTS WILL CAUSE US TO CEASE OPERATIONS.

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

ImmuneRegen's 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. ImmuneRegen's technologies utilizing Homspera has



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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 ImmuneRegen's preclinical studies and clinical trials may not be indicative of future clinical trial results. A commitment of substantial resources to conduct time-consuming research, preclinical studies and clinical trials will be required if it is to develop any products. Delays in planned patient enrollment in ImmuneRegen's clinical trials may result in increased costs, program delays or both. None of ImmuneRegen's 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, ImmuneRegen's potential products may not achieve market acceptance. Any products resulting from ImmuneRegen's 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 ImmuneRegen's proposed products. The appearance of any unacceptable toxicity or side effects could interrupt, limit, delay or abort the development of any of ImmuneRegen's proposed products or, if previously approved, necessitate their withdrawal from the market.

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

Clinical testing, manufacture, promotion, export and sale of ImmuneRegen's 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 ImmuneRegen 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. ImmuneRegen may not receive necessary FDA clearances for any of its 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 ImmuneRegen's 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. ImmuneRegen may encounter significant delays or excessive costs in its 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. ImmuneRegen 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.

In addition, 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

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of a product or withdrawal of the product from the market, as well as possible civil or criminal sanctions.

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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 subject manufacturers to possible FDA regulatory action and as a result, may have a material adverse effect on ImmuneRegen. ImmuneRegen, or its 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 ImmuneRegen.

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.

Marketing any drug products outside of the United States will subject ImmuneRegen to numerous and varying foreign regulatory requirements governing the design and conduct of human clinical trials and marketing approval. Additionally, ImmuneRegen's ability to export drug candidates outside the United States on a commercial basis will be subject to the receipt from the FDA of export permission, which may not be available on a timely basis, if at all. Approval procedures vary among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Foreign regulatory approval processes include all of the risks associated with obtaining FDA approval set forth above, and approval by the FDA does not ensure approval by the health authorities of any other country.

TECHNOLOGICAL CHANGE AND COMPETITION MAY RENDER IMMUNEREGEN'S POTENTIAL PRODUCTS OBSOLETE.

The life science industry continues to undergo rapid change, and competition is intense and is expected to increase. Competitors may succeed in developing technologies and products that are more effective or affordable than any that ImmuneRegen is developing or that would render ImmuneRegen's technology and proposed products obsolete or noncompetitive. Most of ImmuneRegen's competitors have substantially greater experience, financial and technical resources and production, marketing and development capabilities than it. Accordingly, some of ImmuneRegen's competitors may succeed in obtaining regulatory approval for products more rapidly or effectively than it, or technologies and products that are more effective and affordable than any that ImmuneRegen is developing.

IMMUNEREGEN'S LACK OF COMMERCIAL MANUFACTURING AND MARKETING EXPERIENCE MAY PREVENT IT FROM SUCCESSFULLY COMMERCIALIZING PRODUCTS.

ImmuneRegen has not manufactured any of its products in commercial quantities. ImmuneRegen 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. Even if Homspera is successfully developed and receives FDA approval, ImmuneRegen has not demonstrated the capability to manufacture Homspera in commercial quantities. ImmuneRegen has not

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demonstrated the ability to manufacture Homspera in large-scale clinical quantities. ImmuneRegen expects to rely on third parties for the final activation step of the Homspera manufacturing process. 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 ImmuneRegen could establish other manufacturing capacity on a timely basis.

IMMUNEREGEN HAS NO EXPERIENCE IN THE SALES, MARKETING AND DISTRIBUTION OF PHARMACEUTICAL OR BIOTECHNOLOGY PRODUCTS. THUS, IMMUNEREGEN'S PROPOSED PRODUCTS MAY NOT BE SUCCESSFULLY COMMERCIALIZED EVEN IF THEY ARE DEVELOPED AND APPROVED FOR COMMERCIALIZATION.

The manufacturing process of ImmuneRegen's proposed products is expected to involve a number of steps and requires compliance with stringent quality control specifications imposed by ImmuneRegen and by the FDA. Moreover, it is expected that ImmuneRegen's proposed products may be manufactured only in a facility that has undergone a satisfactory inspection and certification by the FDA. For these reasons, ImmuneRegen would not be able to quickly replace its manufacturing capacity if we were unable to use its manufacturing facilities as a result of a fire, natural disaster (including an earthquake), equipment failure or other difficulty, or if such facilities are deemed not in compliance with the GMP requirements, and the noncompliance could not be rapidly rectified. ImmuneRegen's inability or reduced capacity to manufacture its proposed products would prevent it from successfully commercializing its proposed products.

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

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

ImmuneRegen's 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 it 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.

IMMUNEREGEN'S SUCCESS WILL DEPEND UPON THE ACCEPTANCE OF HOMSPERA BY THE MEDICAL COMMUNITY.

ImmuneRegen's ability to market and commercialize Homspera depends on the acceptance and utilization of Homspera by the medical community. ImmuneRegen

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will need to develop commercialization initiatives designed to increase awareness about it and Homspera among targeted audiences, including public health activists and community-based outreach groups in addition to the investment community. Currently, ImmuneRegen has not developed any such initiatives. Without such acceptance of Homspera, the product upon which ImmuneRegen expects to be substantially dependent, ImmuneRegen may not be able to successfully commercialize Homspera or generate revenue.

### PRODUCT LIABILITY EXPOSURE MAY EXPOSE IMMUNEREGEN TO SIGNIFICANT LIABILITY.

ImmuneRegen faces an inherent business risk of exposure to product liability and other claims and lawsuits in the event that the development or use of its technology or prospective products is alleged to have resulted in adverse effects. ImmuneRegen may not be able to avoid significant liability exposure. ImmuneRegen may not have sufficient insurance coverage, and ImmuneRegen 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 its products. A product liability claim could hurt its financial performance. Even if ImmuneRegen avoids liability exposure, significant costs could be incurred that could hurt its financial performance.

IF IMMUNEREGEN FAILS TO ATTRACT AND RETAIN CONSULTANTS AND EMPLOYEES, ITS GROWTH COULD BE LIMITED AND ITS COSTS COULD INCREASE, WHICH MAY ADVERSELY AFFECT ITS RESULTS OF OPERATIONS AND FINANCIAL POSITION.

ImmuneRegen's future success depends in large part upon its ability to attract and retain highly skilled executive-level management and scientific personnel. The competition in the scientific industry for such personnel is intense, and ImmuneRegen cannot be sure that it will be successful in attracting and retaining such personnel. Most of ImmuneRegen's consultants and employees and several of its executive officers began working for ImmuneRegen recently, and all employees are subject to "at will" employment. Most of ImmuneRegen's consultants and employees are not subject to non-competition agreements. ImmuneRegen cannot guarantee that it will be able to replace any of its management personnel in the event their services become unavailable.

IMMUNEREGEN'S PATENTS AND PROPRIETARY TECHNOLOGY MAY NOT BE ENFORCEABLE AND THE PATENTS AND PROPRIETARY TECHNOLOGY OF OTHERS MAY PREVENT IMMUNEREGEN FROM COMMERCIALIZING PRODUCTS.

Although ImmuneRegen believes its patents to be protected and enforceable, the failure to obtain meaningful patent protection products and processes would greatly diminish the value of its potential products and processes.

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

The patent positions of biotechnology and pharmaceutical companies are often highly uncertain and involve complex legal and factual questions. Therefore, the breadth of claims allowed in biotechnology and pharmaceutical patents cannot be predicted. ImmuneRegen also relies upon non-patented trade secrets and know how, and others may independently develop substantially equivalent trade secrets or know how. ImmuneRegen also relies on protecting our proprietary technology in part through confidentiality agreements with its current and former corporate collaborators, employees, consultants and certain contractors. These agreements may be breached, and ImmuneRegen may not have adequate remedies for any such

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breaches. In addition, ImmuneRegen's trade secrets may otherwise become known or independently discovered by ImmuneRegen's competitors. Litigation may be necessary to defend against claims of infringement, to enforce ImmuneRegen's patents or to protect trade secrets. Litigation could result in substantial costs and diversion of management efforts regardless of the results of the litigation. An adverse result in litigation could subject ImmuneRegen to significant liabilities to third parties, require disputed rights to be licensed or require ImmuneRegen to cease using certain technologies.

IMMUNEREGEN'S PRODUCTS AND SERVICES COULD INFRINGE ON THE INTELLECTUAL PROPERTY RIGHTS OF OTHERS, WHICH MAY CAUSE IT TO ENGAGE IN COSTLY LITIGATION AND, IF IS NOT SUCCESSFUL, COULD CAUSE IT TO PAY SUBSTANTIAL DAMAGES AND PROHIBIT IT FROM SELLING OUR PRODUCTS OR SERVICING IMMUNEREGEN'S CLIENTS.

ImmuneRegen cannot be certain that its technology and other intellectual property does not infringe upon the intellectual property rights of others. Authorship and priority of intellectual property rights may be difficult to verify. Because patent applications in the United States are not publicly disclosed until the patent is issued, applications may have been filed which relate to services similar to those offered by ImmuneRegen. ImmuneRegen may be subject to legal proceedings and claims from time to time in the ordinary course of its business, including claims of alleged infringement of the trademarks and other intellectual property rights of third parties.

If ImmuneRegen's products violate third-party proprietary rights, it cannot assure you that it 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 it from providing services. Such claims could severely harm ImmuneRegen's financial condition and ability to compete.

HAZARDOUS MATERIALS AND ENVIRONMENTAL MATTERS COULD EXPOSE IMMUNEREGEN TO SIGNIFICANT COSTS.

ImmuneRegen may be required to incur significant costs to comply with current or future environmental laws and regulations. Although ImmuneRegen does not currently manufacture commercial quantities of its proposed products, it does produce limited quantities of these products for its clinical trials. ImmuneRegen's research and development and manufacturing processes involve the controlled storage, use and disposal of hazardous materials, biological hazardous materials and radioactive compounds. ImmuneRegen is 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 ImmuneRegen believes that its safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, the risk of contamination or injury from these materials cannot be completely eliminated. In the event of an incident, ImmuneRegen 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 ImmuneRegen's operations, business and assets.

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RISKS RELATED TO CAPITAL STRUCTURE

IMMUNEREGEN'S STOCK PRICE IS VOLATILE AND COULD DECLINE IN THE FUTURE.

The price of ImmuneRegen's common stock has been volatile in the past and will likely continue to fluctuate in the future. The stock market in general and the

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market for shares of life science companies in particular have experienced extreme stock price fluctuations. In some cases, these fluctuations have been unrelated to the operating performance of the affected companies. Many companies in the life science and related industries have experienced dramatic volatility in the market prices of their common stock. The Registrant believes that a number of factors, both within and outside our control, could cause the price of the Registrant's common stock to fluctuate, perhaps substantially. Factors such as the following could have a significant adverse impact on the market price of the ImmuneRegen's common stock:

- o The Registrant's ability to obtain additional financing and, if available, the terms and conditions of the financing;
- o ImmuneRegen's financial position and results of operations;
- o The results of preclinical studies and clinical trials by ImmuneRegen, its collaborators or its competitors;
- o Concern as to, or other evidence of, the safety or efficacy of ImmuneRegen's proposed products or its competitors' products;
- o Announcements of technological innovations or new products by ImmuneRegen or its competitors;
- o U.S. and foreign governmental regulatory actions;
- o Actual or anticipated changes in drug reimbursement policies;
- o Developments with ImmuneRegen's collaborators, if any;
- o Developments concerning patent or other proprietary rights of ImmuneRegen or its competitors (including litigation);
- o Status of litigation;
- o Period-to-period fluctuations in ImmuneRegen's operating results;
- o Changes in estimates of the combined company's performance by any securities analysts;
- o New regulatory requirements and changes in the existing regulatory environment;
- o Market conditions for life science stocks in general.

THERE IS NO ASSURANCE OF AN ESTABLISHED PUBLIC TRADING MARKET.

Although ImmuneRegen's common stock trades on the NASD OTC Bulletin Board, a regular trading market for the securities may not be sustained in the future. 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 OTC Bulletin Board is an inter-dealer, Over-The-Counter market that provides significantly less liquidity than the NASD's automated quotation system (the "NASDAQ Stock Market"). Quotes for stocks included on the OTC Bulletin Board 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 OTC Bulletin Board 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. Market prices for ImmuneRegen's common stock will be influenced by a number of factors, including:

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- o The issuance of new equity securities pursuant to a future offering;
- o Changes in interest rates;
- o Competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- o Variations in quarterly operating results;

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- o Change in financial estimates by securities analysts;
- o The depth and liquidity of the market for ImmuneRegen's common stock;
- o Investor perceptions of our company and the technologies industries generally; and
- o General economic and other national conditions.

IMMUNEREGEN'S COMMON STOCK IS CONSIDERED A "PENNY STOCK."

ImmuneRegen's 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. These include but are not limited to the following: (i) the stock trades at a price less than five dollars (\$5.00) per share; (ii) it is NOT traded on a "recognized" national exchange; (iii) it is NOT quoted on the NASDAQ Stock Market, or even if so, has a price less than five dollars (5.00) per share; or (iv) is issued by a company with net tangible assets less than \$2,000,000, if in business more than a continuous three years, or with average revenues of less than \$6,000,000 for the past three years. The principal result or effect of being designated a "penny stock" is that securities broker-dealers cannot recommend the stock but must trade in it on an unsolicited basis.

BROKER-DEALER REQUIREMENTS MAY AFFECT TRADING AND LIQUIDITY.

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.

Potential investors in ImmuneRegen's common stock are urged to obtain and read such disclosure carefully before purchasing any shares that are deemed to be "penny stock." Moreover, Rule 15g-9 requires broker-dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any penny stock to that investor. This procedure requires the broker-dealer to (i) obtain from the investor information concerning his or her financial situation, investment experience and investment objectives; (ii) reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has sufficient knowledge and experience as to be reasonably capable of evaluating the risks of penny stock transactions; (iii) provide the investor with a written statement setting forth the basis on which the broker-dealer made the determination in (ii) above; and (iv) receive a signed and dated copy of such statement from the investor, confirming that it accurately reflects the investor's financial situation, investment experience and investment objectives. Compliance with these requirements may make it more difficult for holders of ImmuneRegen's

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common stock to resell their shares to third parties or to otherwise dispose of them in the market or otherwise.

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

ImmuneRegen's 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 ImmuneRegen's 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 ImmuneRegen's business, even if such a transaction would be beneficial to other stockholders.

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

Certain of ImmuneRegen's stockholders have the right to hold securities registered pursuant to registration rights agreements. The sale or the proposed sale of substantial amounts of ImmuneRegen's equity securities or convertible debt securities may adversely affect the market price of its common stock and its stockholders may experience substantial dilution. Also, any new equity securities issued may have greater rights, preferences or privileges than ImmuneRegen's existing common stock.

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IMMUNEREGEN CAN ISSUE SHARES OF PREFERRED STOCK WITH RIGHTS SUPERIOR TO THOSE OF THE HOLDERS OF OUR COMMON STOCK. SUCH ISSUANCES CAN DILUTE THE TANGIBLE NET BOOK VALUE OF SHARES OF THE REGISTRANT'S COMMON STOCK.

ImmuneRegen's Board of Directors is authorized to issue up to 10,000,000 shares of blank check preferred stock with rights that are superior to the rights of the stockholders of its common stock, at a purchase price substantially lower than the market price of shares of its common stock without stockholder approval.

WE HAVE NO INTENTION TO PAY DIVIDENDS.

ImmuneRegen has never declared or paid any dividends on its securities. ImmuneRegen currently intends to retain its earnings for funding growth and, therefore, does not expect to pay any dividends in the foreseeable future.

### 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



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Evaluation Date, such controls and procedures were effective in ensuring that required information will be disclosed on a timely basis in our periodic reports filed under the Exchange Act.

### (b) Changes in internal controls

There were no significant changes to our internal controls or in other factors that could significantly affect internal controls subsequent to the Evaluation Date.

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

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

None.

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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 November 22, 2004.

IR BioSciences Holdings, Inc.

By:

/s/ Michael Wilhelm

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Michael Wilhelm  
President, Chief Executive Officer