IR BIOSCIENCES HOLDINGS INC

Form 10OSB August 23, 2004

FORM 10-QSB

SECURIT	IES	AND	EXC	CHAN	IGE	COMMISSION
W	ASH1	INGTO	οN,	D.	С.	20549

(X) Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the quarterly period ended June 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 (I.R.S. Employer incorporation or organization) 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

> Yes X No

requirements for the past 90 days.

The number of shares outstanding of Registrant's common stock as of August 17,

2004 was 30,168,716.

IR BIOSCIENCES, INC. AND SUBSIDIARY

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ITEM 1. FINANCIAL INFORMATION

IR BioSciences Holdings, Inc. and Subsidiary
(A Development Stage Company)
Consolidated Balance Sheet
June 30, 2004
(Unaudited)

Assets

Current assets Cash and cash equivalents Prepaid services and other assets	\$	5,208 4,800
Total current assets		10,008
Licensed proprietary rights, net Furniture and equipment, net		7,783 2,456
Total assets	\$	20,247
Liabilities and Deficiency in Stockholders' Equity		
Current liabilities Current portion of notes payable, net of discount Accounts payable and accrued liabilities		934,011 787,652
Total current liabilities	1,	721,663
Long-term notes payable, net of discount		30,659
Commitments and Contingencies		
Deficiency in Stockholders' Equity 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; 28,319,500 shares issued		
and outstanding at June 30, 2004	4	28,319
Additional paid-in capital Deferred compensation		270,874 187,344)
Deficit Accumulated during the Development Stage		843,924)
Total deficiency in stockholder's equity	(1,	732,075)
Total liabilities and deficiency in stockholders' equity		20,247

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

IR BioSciences Holdings, Inc. and Subsidiary
(A Development Stage Company)
Consolidated Statements of Operations
(Unaudited)

	For the Months June	For th Months June		
	2004		2004	
Revenues	\$	\$	\$	
Operating expenses: Selling, general and administrative expenses Merger fees and costs Financing cost	1,574,415 	280,872 	2,505,489 	
Total operating expenses	1,574,415	280,872	· ·	
Operating loss	(1,574,415)	(280,872)	(2,505,489)	
Interest expense	131,737	22 , 642	435,815	
Total other expense	131,737	22,642		
Loss before income taxes	(1,706,152)	(303,514)	(2,941,304)	
Provision for income taxes				
Net loss	\$ (1,706,152) =======			
Net loss per share - basic and diluted	\$ (0.06)	\$ (0.02) ======		
Weighted average shares outstanding - basic and diluted	27,474,445	15,425,852	26,163,266	

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

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

	For the Six Months Ended June 30,					
		2004		2003	June 30, 2004	
Cash flows from operating activities: Net loss Adjustments to reconcile net loss to to net	\$(2,941,304)	\$	(391,716)	\$(4,843,924)	
<pre>cash used in operating activities: Non-cash compensation Amortization of deferred compensation</pre>		1,912,027 		19,779 9,000		
Interest expense Amortization of discount on notes payable Depreciation and amortization Changes in operating assets and liabilities:		37,545 399,222 12,053		10,306 6,258	106,169 701,524 24,815	
Prepaid services and other assets Accounts payable and accrued expenses		31,043		(49,843)	(4,799) 678,932	
Net cash used in operating activities		(305, 483)		(301,192)	(1,338,646)	
Cash flows from investing activities: Acqisition of property and equipment Increase in cash related to acquisition Increase in prepaid acquisition costs		 		(3,304) (350,000) (90,000)	(3,304)	
Net cash used in investing activities				(443,304)	(3,304)	
Cash flows from financing activities: Proceeds from notes payable Principal payments on notes payable Shares of stock issued for cash Officer repayment of amounts paid on his behal Cash paid on amount due to officer	f	31,200		795,000 65,000 (14,381)	19,880	
Net cash provided by financing activities		300,157		845 , 619	1,347,158	
Net increase in cash and cash equivalents		(5,326)		101,123	5,208	
Cash and cash equivalents at beginning of period		10,534		32,155		
Cash and cash equivalents at end of period	\$	5 , 208		133 , 278	\$ 5,208	
Cash paid during the period for: Interest		4,553 			\$ 46,346 ======	

Taxes

\$ -- \$ -- \$ --------

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

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

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 maket 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 is 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.

The accompanying notes are an integral part of these 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)

			Additional	Dofo
		Amount		Defe Compen
Balance at October 30, 2002 (date of inception)		\$	\$	\$
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	(
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 (reflective of stock splits)	18,257,042	18,257	31,776	(
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 associated with notes issued in June 2003			60,560	
Amortization of deferred compensation				
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	
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	

The accompanying notes are an integral part of these 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) (continued)

	Common Stock		Additional Paid-In	Defe	
	Shares	Amount		Compen	
Shares granted at \$1.00 per share pursuant to the Senior Note Agreement in January 2004	600,000	600	599 , 400	(60	
Shares issued in January 2004 at \$1.00 per share to a consultant for services	800,000	800	799,200	(80	

Shares issued in February 2004 to a consultant at \$0.62 per share for services	40,000	40	24,760	(2
Shars issued in March 2004 to a consultant at \$0.40 per share for services	1,051,600	1,052	419,588	(42
Shares issued in March 2004 to a consultant at \$0.50 per share for services	500,000	500	249,500	(25
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 for services	45,800	45	29,267	
Amortization of deferred compensation through March 2004				68
Shares to be issued to a consultant at \$0.41 per share for contracted services				(8
Shares granted pursuant to the New Senior Note Agreement in April 2004	600,000	600	149,400	(15
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	
Benefial 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 dilligence 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	(50
Benefial 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				95
Net loss for the six months ended June 30, 2004				
Balance at June 30, 2004	28,319,500		\$4,270,874	-
		=	=	===

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

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

JUNE 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 results from operations for the three-month and six-month periods ended June 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

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

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.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2004

(Unaudited)

NOTE 1 - SUMMARY OF ACCOUNTING POLICIES (CONTINUED)

Reverse Acquisition

On July 20, 2003 ImmuneRegen Biosciences Inc. ("ImmuneRegen")entered into an Agreement of Plan and Merger ("Agreement") with GPN Network, Inc. ("GPN") an inactive publicly registered shell corporation with no significant assets or operations. In accordance with SFAS No. 141, the Company was the acquiring entity. While the transaction is accounted for using the purchase method of accounting, in substance the Agreement is a recapitalization of the Company's capital structure.

For accounting purposes, the Company has accounted for the transaction as a reverse acquisition and the Company shall be the surviving entity. The total purchase price and carrying value of net assets acquired was \$ 0. From July 2001 until the date of the Agreement the Company was inactive. The Company did not recognize goodwill or any intangible assets in connection with the transaction.

Effective with the Agreement, all previously outstanding common stock, preferred stock, options and warrants owned by the Company's shareholders were exchanged for an aggregate of 21,063,170 (post-split) shares of GPN common stock. The value of the stock that was issued was the historical cost of GPN's net tangible assets, which did not differ materially from their fair value.

Effective with the Agreement, GPN changed its name to IR Biosciences Holdings $T_{\rm RC}$

The accompanying financial statements present the historical financial condition, results of operations and cash flows of the Company prior to the merger with GPN.

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.

ImmuneRegen BioSciences Asia PTE. LTD.

ImmuneRegen BioSciences Asia PTE. LTD. ("IRB Asia") was formed by the Company's Chief Executive Officer and by a Founder of the Company on May 6, 2004, for the purpose of licensing the Company's proprietary compound Homspera in Asia. As of June 30, 2004, the Company held a minority interest in IRB Asia. At August 23, 2004, the Company was in the process of transferring the shares of IRB Asia currently held by the Chief Executive and by the Founder to the Company, making IRB Asia a wholly-owned subsidiary of the Company. As of June 30, 2004, IRB Asia was inactive.

Going Concern

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

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

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2004

(Unaudited)

NOTE 1 - SUMMARY OF ACCOUNTING POLICIES (CONTINUED)

Interim Financial Statements

The accompanying balance sheet as of June 30, 2004, the statements of operations for the three months and six months ended June 30, 2004 and 2003, and for the period from inception to June 30, 2004, and the statements of cash flows for the six months ended June, 2004 and 2003, and from the period of inception (October 30, 2002) to June 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

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 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.

NOTE 2 - RELATED PARTY TRANSACTIONS

Founder's Consulting Fees

During the three months and six months ended June 30, 2004, the Company accrued \$30,000 and \$60,000, respectively, in consulting fees payable to two of the Company's founders.

InOne Contract

The Company has entered into a series of contracts for marketing, website development, and website hosting with InOne Advertising "(In-One"), a company run by the spouse of the Company's CEO. Pursuant to these contracts, during the six months ended June 30, 2004, the Company issues 45,800 shares (post-split) of its common stock to with a value of \$29,312 to In-One.

Office Lease

The Company subleases its office space from Foresight Capital Partners, a company controlled by the Company's CEO. The rent cost is passed through to the Company at the same rental rate that Foresight Capital Partners is charged by the facility's primary landlord. Rent expense amounted to \$8,568 and \$17,136, respectively, for the three and six month periods ended June 30, 2004.

Shares issued to Chief Financial Officer

In April 2004, the Company issued 200,000 shares (post-split) of its common stock to the Company's Chief Financial Officer as payment for services performed from June 2003 through June 2004.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2004

(Unaudited)

NOTE 2 - RELATED PARTY TRANSACTIONS (CONTINUED)

Stratum Consulting Agreement

On April 1, 2004, the Company entered into a consulting agreement with Stratum Consulting Group, Inc. ("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.

Founder and CEO Warrants

On May 6, 2004, the Company granted a five-year warrant to purchase 500,000 shares (post-split) of the Company's common stock at \$0.25 per share to one of the Company's founders and to the Company's CEO. The Company valued these warrants using the Black-Scholes valuation model, and charged the entire amount of \$124,411 for each warrant to the Company's statement of operations for the three month period ending June 30, 2004.

NOTE 3 - DEBT

Amended Secured Convertible Promissory Notes

During the three and six month periods ended June 30, 2004, the Company amortized to interest expense \$11,855 and \$105,768, respectively, of the discount associated with its Amended Convertible Promissory Notes Payable (the "Amended Notes"). At June 30, 2004, the total principal amount due pursuant to the Amended Notes is \$245,000. The total discount remaining on the Amended Notes at June 30, 2004 is \$0. In June 2004, the terms of the Amended Notes were extended to August, 2004. Interest accrued for the three and six months ended June 30, 2004 was \$4,818 and \$9,636, respectively. Total accrued interest due on the Amended Notes at June 30, 2004 was \$13,968. At June 30, 2004, five of the Amended Notes were in default as they had not been paid within their terms. With the exception of one note in the principal amount of \$100,000, the Company has negotiated extensions to the terms of these notes. The Company is not in compliance with the provisions of the \$100,000 note.

Fourth Quarter Secured Convertible Promissory Notes

During the three months ended June 30, 2004, the Company converted one of the Fourth Quarter Secured Convertible Notes (the "Fourth Quarter Notes") in the amount of \$35,000 into 350,000 shares (post-split) of common stock, and made principal payments of \$4,000 on another Fourth Quarter Note. During the six months ended June 30, 2004, the Company made principal payments of an additional \$15,000 on the Fourth Quarter Notes. During the three and six months ended June 30, 2004, the Company amortized to interest expense \$\$40,100 and \$233,428, respectively, of the discount associated with the Fourth Quarter Notes. At June 30, 2004, the total discount remaining on the Fourth Quarter Notes was \$0, and the total principal amount due pursuant to the Fourth Quarter Notes was \$337,000. Interest accrued for the three and six months ended June 30, 2004 was \$7,160 and \$14,827, respectively. Total accrued interest due on the Fourth Quarter Notes at June 30, 2004 was \$21,535. At June 30, 2004, eight of the Fourth Quarter Notes were in default as they had not been paid within their terms. The Company has negotiated extensions to the terms of these notes, and at August 23, 2004, these notes are no longer in default.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2004

(Unaudited)

NOTE 3 - DEBT (CONTINUED)

Senior Secured Promissory Notes

In January 2004, the Company entered into a \$150,000 Senior Secured Promissory Note Agreement (the "Senior Note"). The Senior Note bears interest at the rate of 12% per annum and has a term of 90 days. Interest accrued for the three and six months ended June 30, 2004 was \$3,100 and \$4,500, respectively. The Senior Note is senior secured indebtedness of the Company and is secured by certain collateral. As additional incentive to enter into the Senior Note, the Company provided 600,000 shares (post-split) of the Company's common stock valued at \$600,000.

In April, 2004, the Senior Note was paid in full and the Company entered into a new Senior Secured promissory Note Agreement 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 six months period ending June 30, 2004 was \$3,251. 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.

Other Notes Payable

At June 30, 2004, the Company has outstanding eight other notes payable in the aggregate principal amount of \$211,581. These notes bear interest at rates ranging from 6% to 12% per annum. During the three and six months ended June 30, 2004, interest of \$2,059 and \$3,015, respectively, was accrued on these notes. Six notes with an aggregate principal amount of \$176,581 are due within one year at June 30, 2004. Two notes with an aggregate amount of \$35,000 are due twenty-four months from inception, or April and May 2006. During the three months ended June 30, 2004, the Company received cash proceeds of \$137,100 pursuant to these notes, and made principal payments of \$5,000. Total accrued interest on these notes at June 30, 2004 is \$3,705. The Company recognized an aggregate discount of \$13,411 on these notes due to various beneficial conversion features and warrants. During the three and six months ended June 30, 2004, the Company amortized \$7,527 of this aggregate discount.

Demand Loan

In April 2004, the Company $\,$ received a \$30,000 demand loan from an investor. In August 2004, this loan was converted into 200,000 shares of common stock.

NOTE 4 - EQUITY

Stock Split

On April 6, 2004, the Company effected a two-for-one forward split of its common stock. The number of shares of common stock outstanding immediately prior to the reverse split was 13,272,250; the number of shares of common stock outstanding

immediately after the reverse split was 26,544,500. The accompanying financial statements reflect the effect of this stock split.

Common Stock

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 \$600,000of this amount, respectively, had been charged to non-cash compensation.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2004

(Unaudited)

NOTE 4 - EQUITY (CONTINUED)

Common Stock (continued)

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.

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, had been charged to non-cash compensation.

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

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

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

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

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

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

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

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

JUNE 30, 2004

(Unaudited)

NOTE 4 - EQUITY (CONTINUED)

Common Stock (continued)

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.

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

April Consulting Agreements

In April 2004, the Company entered into two agreements with a consultant which

called for the issuance of an aggregate of 850,000 shares (post-split) of the Company's common stock. In July 2004, these agreements were voided; the shares were not issued and are not due to be issued.

Notes Payable Extensions

At June 30, the Company was in default of fourteen of its notes payable in the aggregate principal amount of \$561,000. With the exception of one note in the principal amount of \$100,000, the Company has negotiated extensions to the terms of these notes. The Company is not in compliance with the provisions of the \$100,000 note.

Common Stock Issued

In July and August 2004, the Company issued an aggregate of 625,776 shares of common stock pursuant to various consulting agreements.

In July and August 2004, the Company issued 120,000 shares of common stock in partial satisfaction of the agreement to extend the term of the Senior Note Payable.

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

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

Special note regarding forward-looking statements

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

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

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

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

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

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

Our goal is to enter into overseas licensing and royalty agreements for its applications while awaiting approval by the FDA in the Unites 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.

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 JUNE 30, 2004

Revenue

We are in the development stage and have no revenue.

Selling, General and Administrative Expenses _____

Selling, general and administrative expenses ("SG&A") were \$1,574,415 for the three months ended June 30, 2004 which is an increase of \$1,293,543 or 461% compared to SG&A of \$280,872 for the three months ended June 30, 2003. The increase is primarily comprised of non-cash compensation, legal and accounting fees, officer wages, research and development costs, consulting fees, and contract labor. We expect these costs to increase in the coming year as we continue to utilize non-cash compenation in order to conserve our cash, and as we seek further financing, implement our plan of operation, and build out our administrative and operational infrastructure.

Interest expense

Interest expense was \$131,737 for the three months ended June 30, 2004, an increase of \$109,095 or 481% compared to interest expense of \$22,642 for the three months ended June 30, 2003. This amount consists of amortization of the discount on notes payable of \$112,939 and interest on notes payable of \$18,798. We expect interest expense may continue to increase over the next twelve months if the level of our debt increases.

Net loss

For the reasons above, the net loss for the three months ended June 30, 2004 was \$1,706,152, an increase of \$1,402,638 or 462% compared to a net loss of \$303,514 for the three months ended June 30, 2003. We expect our losses to continue and to increase over the coming twelve months. We do not expect to expect to begin to generate revenue in the next twelve months, and costs are likely to increase as we move our products through the testing and approval phases, and as we continue to build out our corporate infrastructure.

RESULTS OF OPERATIONS - SIX MONTHS ENDED JUNE 30, 2004

Revenue

We are in the development stage and have no revenue.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were \$2,505,489 for the six months ended June 30, 2004 which is an increase of \$2,136,415 or 579% compared to SG&A of \$2,136,415 for the six months ended June 30, 2003. This expense is primarily comprised of non-cash compensation of \$1,912,026, legal and accounting fees of \$185,711, officer wages of \$87,500, research and development costs of \$61,807, consulting fees of \$65,000, and contract labor of \$41,503.

Interest expense

Interest expense was \$435,815 for the six months ended June 30, 2004, an increase of \$413,173 or 1,825% compared to interest expense of \$22,642 for the six months ended June 30, 2003. This amount consists of amortization of the discount on notes payable of \$401,133 and interest on notes payable of \$34,682.

Net loss

For the reasons above, the net loss for the six months ended June 30, 2004 was \$2,941,304, an increase of \$2,549,588 or 651% compared to a net loss of \$391,716 for the six months ended June 30, 2003.

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LIQUIDITY AND CAPITAL RESOURCES

At June 30, 2004, we had current assets of \$10,008 consisting of cash of \$5,208 and prepaid services of \$4,800. Also at June 30, 2004, we had current liabilities of \$1,721,663, consisting of notes payable net of discount of \$934,011 and accounts payable and accrued liabilities of \$787,652. This results in negative working capital of \$1,711,655. During the six months ended June 30, 2004, the Company used cash in operating activities of \$305,483. From the date of inception (October 30, 2002) to June 30, 2004, the Company has had a net loss of \$4,843,924 and has used cash of \$1,338,646 in operating activities. We met our cash requirements during this period through the private placement of \$127,201 of our common stock and \$1,219,957 from the issuance of notes payable, net of repayments.

At June 30, 2004, we were in default of fourteen of our Notes Payable in the aggregate amount of \$561,000 plus accrued interest of \$33,864. We have negotiated extensions to the terms of these notes and at August 23, 2004, we are

current with all of our obligations under these notes.

We currently have 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, we have financed our 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 developmentIt is expected that in order to implement its business plan, we 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 our operations and development to the level of capitalization , we believe we have 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 would have a material adverse effect on our business, results of operations , liquidity and financial condition.

At June 30, the Company was in default of fourteen of its notes payable in the aggregate principal amount of \$561,000. With the exception of one note in the principal amount of \$100,000, the Company has negotiated extensions to the terms of these notes. The Company is not in compliance with the provisions of the \$100,000 note.

Product Research and Development

We anticipate performing further research and development of the applications of our proprietary compound "Homspera" during the next twelve months. These projected expenditures are dependent upon our generating revenues and obtaining sources of financing in excess of our existing capital resources. There is no guarantee that we will be successful in raising the funds required or generating revenues sufficient to fund the projected costs of research and development during the next 12 months.

Acquisition of Plant and Equipment and Other Assets

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

Number of Employees

From our inception through the period ended June 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 incur additional cost for personnel.

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Trends, Risks and Uncertainties

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

RISK FACTORS

The actual results of the combined company may differ materially from those anticipated in these forward-looking statements. The Registrant and ImmuneRegen 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 those not currently believed to be important to you, if they materialize, also may adversely affect the combined company.

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 June 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 thereafter for the foreseeable future. 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.

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

Our independent certified public accountants have stated in their report included in our Form 10-KSB that we have incurred substantial losses and negative cash flows for the period of inception of October 30, 2002 to June 30, 2004 and due to that and a lack of operational history, among other matters, there has been raised substantial doubt about our 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 may materially and adversely affect our ability to raise capital, our relationship with potential suppliers and customers, and have other unforeseen effects.

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

ImmuneRegen requires substantial working capital to fund its operations. Since we do 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 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.

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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 it is unable to do so, ImmuneRegen's business will not be successful.

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 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.

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The results of ImmuneRegen's preclinical studies and clinical trials may not be indicative or future clinical trial results. A commitment of substantial resources to conduct time-consuming research, preclinical studies and clinical trials will be required if 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 Unites 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 pre-market 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 of a product or withdrawal of the product from the market, as well as possible civil or criminal sanctions.

Among the other requirements for regulatory approval is the requirement that prospective manufacturers conform to the FDA's Good Manufacturing Practices, or GMP, requirements. In complying with the FDA's GMP requirements, manufacturers must continue to expend time, money and effort in production, record keeping and quality control to assure that products meet applicable specifications and other requirements. Failure to comply and maintain compliance with the FDA's GMP requirements subjects manufacturers to possible FDA regulatory action and as a result, may have a material adverse effect on 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.

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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 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

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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.

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 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.

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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.

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 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 do 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.

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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 propriety 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.

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 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;

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- 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:

- 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;
- 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

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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 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 form 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.

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.

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WE HAVE NO INTENTION TO PAY DIVIDENDS.

ImmuneRegen has never declared or paid any dividends on its securities. ImmuneRegen currently intends to retain its earning 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 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.

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 June 30, 2004, we issued a total of 1,775,000 shares, net of cancellations (post-split) of our Common Stock to officers and consultants for services rendered. 325,000 of these shares (post-split) are registered with Form S-8 of the Securities and Exchange Commission. 1,450,000 of these shares (post-split) are considered exempt from registration by reason of Section 4(2) of the Securities Act of 1933. (d) None.
- Item 3. Defaults Upon Senior Securities None.

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- Item 4: Submission of Matters to a Vote of Securities Holders None.
- Item 6. Exhibits and Reports on Form 8-K
- (a) Exhibits
- 31.1 Certification of Chief Executive Officer pursuant to Securities Exchange Act Rule 13a-14(a).

- 31.2 Certification of Chief Financial Officer pursuant to Securities Exchange Act Rule 13a-14(a).
- 32.1 Certification of Chief Executive Officer pursuant to U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Chief Financial Officer pursuant to U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- (b) Reports on Form 8-K

On April 7, 2004, the Company filed a Current Report on Form 8-K, dated April 6, 2004, reporting under Items 5 and 7 the two (2) for one (1) forward split of its common stock effective April 6, 2004.

On May 14, 2004, the Company filed a current report on Form 8-K, dated April 21, 2004, reporting under Items 4 and 7 the change in the Company certifying accountant.

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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 August 20, 2004.

IR BioSciences Holdings, Inc.

By: /s/ Michael Wilhelm

Michael Wilhelm

President, Chief Executive Officer

Date: August 23, 2004