

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

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

FORM 10-QSB/A  
(Amendment No. 1)

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D. C. 20549

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

For the quarterly period ended March 31, 2005

or

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

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

COMMISSION FILE NUMBER: 033-05384

IR BIOSCIENCES HOLDINGS, INC.

(Exact name of Registrant as specified in its charter)

Delaware

13-3301899

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

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

4021 N. 75th Street, Suite 201, Scottsdale, Arizona 85251  
(Address of principal executive offices) Zip Code

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

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

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

Yes X No  
--- ---

The number of shares outstanding of Registrant's common stock as of May 23, 2005 was 69,024,166.

IR BIOSCIENCES HOLDINGS, INC. AND SUBSIDIARY

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## ITEM 1. FINANCIAL INFORMATION

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

IR BioSciences Holdings, Inc. and Subsidiary  
(A Development Stage Company)  
Condensed Consolidated Balance Sheet as of March 31, 2005  
(Unaudited)

	March 31, 2005
	-----
Assets	
Current assets	
Cash and cash equivalents	\$ 1,600,000
Prepaid services and other current assets	7,085
	-----
Total current assets	1,607,085
Licensed proprietary rights, net	7,088
Furniture and equipment, net	6,330

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Total assets	\$ 1,620,503
=====	
Liabilities and Stockholders' Equity	
Current liabilities	
Accounts payable and accrued liabilities	341,210
Current portion of notes payable, net of discount	66,970
-----	
Total current liabilities	408,180
Commitments and Contingencies	
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; 69,024,166 shares issued and outstanding	69,024
Additional paid-in capital	9,244,248
Deferred compensation	(53,425)
Deficit Accumulated during the Development Stage	(8,047,524)
-----	
Total stockholder's equity	1,212,323
-----	
Total liabilities and stockholders' equity	\$ 1,620,503
=====	

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)  
Condensed Consolidated Statement of Operations  
For the three months ended March 31, 2005 and 2004,  
And for the period of inception  
(October 30, 2002) to March 31, 2005  
(Unaudited)

	For the Three Months Ended March 31, 2005	For the Three Months Ended March 31, 2004	Cumulative from Inception (October 30, 2002) to March 31, 2005
	-----	-----	-----
Operating expenses:			
Selling, general and administrative expenses	\$ 838,520	\$ 931,074	\$ 6,428,404
Merger fees and costs	0	0	350,000
Financing cost	0	0	90,000
-----			
Total operating expenses	838,520	931,074	

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Operating loss	(838,520)	(931,074)	6,868,404 (6,868,404)
Other expense:			
Interest expense	977	304,078	1,179,120
	-----	-----	-----
Total other expense	977	304,078	1,179,120
Loss before income taxes	(839,497)	(1,235,152)	(8,047,524)
Provision for income taxes	--	--	--
	-----	-----	-----
Net loss	\$ (839,497)	\$ (1,235,152)	\$ (8,047,524)
	=====	=====	=====
Net loss per share - basic and diluted	\$ (0.01)	\$ (0.05)	\$ (0.27)
	=====	=====	=====
Weighted average shares outstanding - basic and diluted	62,863,440	24,845,493	29,486,331
	=====	=====	=====

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)  
Condensed Consolidated Statement of Stockholders' Equity  
For the period from inception (October 30, 2002) to March 31, 2005  
(unaudited)

	Common Stock		Additional	Deferr
	Shares	Amount	Paid-In Capital	Compensa
	-----	-----	-----	-----
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	(9
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	--	--	--	--
	-----	-----	-----	-----

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Balance at December 31, 2002 (reflective of stock splits)	18,257,042	18,257	31,776	(9
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	--	--	--	9
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 twelve month period 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 condensed consolidated financial statements.

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IR Biosciences Holding, Inc. and Subsidiary  
 (A Development Stage Company)  
 Condensed Consolidated Statement of Stockholders' Equity  
 For the period from inception (October 30, 2002) to March 31, 2005  
 (unaudited) (continued)

	Common Stock		Additional Paid-In Capital	Deferr Compensa
	Shares	Amount		
Shares granted at \$1.00 per share pursuant to the Senior Note Agreement in January 2004	600,000	600	599,400	(600)
Shares issued at \$1.00 per share to a consultant for services rendered in January 2004	800,000	800	799,200	(800)
Shares issued to a consultant at \$0.62 per share for services rendered in February 2004	40,000	40	24,760	(24)
Shares issued to a consultant at \$0.40 per share for services rendered in March 2004	1,051,600	1,051	419,589	(420)
Shares issued to a consultant at \$0.50 per share for services rendered in March 2004	500,000	500	249,500	(250)
Shares sold for cash at \$0.15 per share in March, 2004	8,000	8	1,192	
Shares issued at \$0.50 per share to consultants for services rendered in March 2004	20,000	20	9,980	
Shares issued to a consultant at \$0.40 per share for services rendered in March 2004	2,000	2	798	
Shares issued to consultants at \$0.32 per share for services rendered in March 2004	91,600	92	29,220	
Shares to be issued to consultant at \$0.41 per share in April 2004 for services to be rendered through March 2005	--	--	--	(82)
Shares granted pursuant to the New Senior Note Agreement in April 2004	600,000	600	149,400	(150)
Shares issued to officer at \$0.32 per share for services rendered in April 2004	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	--	--	35,000	
Issuance of warrants to officers and founder for services rendered in May 2004	--	--	269,208	

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Shares to a consultant at \$0.20 per share as a due diligence fee in May 2004	125,000	125	24,875	
Shares issued to a consultant at \$1.00 per share for services to be rendered over twelve months beginning May 2004	500,000	500	499,500	(500)
Beneficial Conversion Feature associated with notes payable issued in June 2004	--	--	3,000	
Issuance of warrants to note holders in April, May, and June 2004	--	--	17,915	
Issuance of warrants to employees and consultants for services rendered in April through June 2004	--	--	8,318	
Shares issued in July to a consultant at \$0.10 for services to be rendered through July 2005	250,000	250	24,750	(250)

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)  
Condensed Consolidated Statement of Stockholders' Equity  
For the period from inception (October 30, 2002) to March 31, 2005  
(unaudited) (continued)

	Common Stock		Additional	Deferr
	Shares	Amount	Paid-In Capital	Compensa
	-----	-----	-----	-----
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	
Shares issued to a consultant in September at \$0.12 to \$0.22 for services rendered through September 2004	127,276	127	16,782	
Shares issued in July to September 2004 as interest on note payable	300,000	300	35,700	
Issuance of warrants with notes payable in July and August 2004	--	--	72,252	
Accrued deferred compensation in August 2004 to a consultant for 100,000 shares at \$0.10 per share, committed but unissued	--	--	--	(100)
Shares issued in August 2004 at \$0.14 to a				

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consultant for services to be performed through October 2004	100,000	100	13,900	(14
Shares issued in August 2004 at \$0.125 per share for conversion of \$30,000 demand loan	240,000	240	29,760	
Shares issued in August 2004 at \$0.16 per share to a consultant for services provided	125,000	125	19,875	
Shares issued to employees at \$0.16 to \$0.25 per share	48,804	49	8,335	
Commitment to issue 100,000 shares of stock to a consultant at \$0.23 per share for services to be provided through September 2005	--	--	--	(23
Sale of stock for cash in October at \$0.125 per share, net of costs of \$298,155	18,160,000	18,160	1,345,763	
Value of warrants issued with sale of common stock in October, net of costs	--	--	607,922	
Issuance of warrant to officer in October	--	--	112,697	
Issuance of stock to investment bankers in October 2004 for commissions earned	4,900,000	4,900	(4,900)	
Conversion of accounts payable to stock in October at \$0.125 per share	1,257,746	1,258	107,382	
Value of warrants issued with accounts payable conversions	--	--	48,579	
Conversion of demand loan to stock in October at \$0.11 per share	93,300	93	10,170	
Forgiveness of notes payable in October 2004	--	--	36,785	
Issuance of stock to officer and director at \$0.125 per share in October for conversion of liability	1,440,000	1,440	122,493	
Value of warrants issued with officer and director conversion of liabilities	--	--	56,067	
Conversion of debt and accrued interest to common stock at \$0.075 to \$0.125 per share	6,703,151	6,703	417,514	
Value of warrants issued with conversion of debt	--	--	191,111	
Conversion of note payable in October into common stock at \$0.075 per share	67,613	68	4,932	

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

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IR Biosciences Holding, Inc. and Subsidiary



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(A Development Stage Company)

Condensed Consolidated Statement of Stockholders' Equity  
For the period from inception (October 30, 2002) to March 31, 2005  
(unaudited) (continued)

	Common Stock		Additional	Deferr
	Shares	Amount	Paid-In Capital	Compensa
Issuance of warrants to note holders in October 2004	--	--	112,562	
Value of shares issued to CFO as compensation	100,000	100	34,900	
Value of warrants issued to members of advisory committees in November and December	--	--	16,348	
Beneficial conversion feature associated with notes payable	--	--	124,709	
Shares issued in error to be cancelled	(9,002)	(9)	9	
Amortization of deferred compensation through December 31, 2004	--	--	--	2,729
Loss for the twelve months ended December 31, 2004	--	--	--	
Balance at December 31, 2004	62,423,388	62,423	7,922,943	(169)
Sale of shares of common stock for cash at \$0.20 per share in March 2005 for warrant exercise, net of costs	6,600,778	6,601	1,184,256	
Value of warrants issued to members of advisory committees			137,049	
Accrued Deferred compensation In February, 2005 to a consultant For 50,000 shares at \$0.65 per share. Committed but unissued.				(32)
Amortization of deferred compensation for three months ended March 31, 2005				149
Loss for the three months ended March 31, 2005				
	69,024,166	\$ 69,024	\$ 9,244,248	\$ (53)

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)  
 Condensed Consolidated Statement of Cash Flows  
 For the three months ended March 31, 2005 and  
 2004, And for the period of inception (October 30, 2002)  
 to March 31, 2005  
 (Unaudited)

	For the Three Months Ended March 31, 2005	For the Three Months Ended March 31, 2004	Cumulati from Incep (October 2002) t March 31,
Cash flows from operating activities:			
Net loss	\$ (839,497)	\$ (1,235,152)	\$ (8,047,5
ADJUSTMENTS TO RECONCILE NET LOSS TO NET CASH USED IN OPERATING ACTIVITIES:			
Non-cash compensation	299,943	688,027	3,699,9
Interest expense	977	953	153,3
Amortization of discount on notes payable	0	287,241	1,006,9
Depreciation and amortization	402	11,651	26,4
Changes in operating assets and liabilities:			
Prepaid services and other assets	(372)	23,543	(7,0
Accounts payable and accrued expenses	(12,424)	89,558	542,6
NET CASH USED IN OPERATING ACTIVITIES	(550,971)	(134,179)	(2,625,3
Cash flows from investing activities:			
Acquisition of property and equipment	0	0	(8,0
NET CASH USED IN INVESTING ACTIVITIES	0	0	(8,0
Cash flows from financing activities:			
Proceeds from notes payable	--	150,000	1,233,5
Principal payments on notes payable and demand loans	(10,000)	(15,000)	(260,0
Shares of stock sold for cash	1,190,857	1,200	3,259,9
Officer repayment of amounts paid on his behalf			19,8
Cash paid on behalf of officer			(19,8
Cash paid on amount due to officer			
NET CASH PROVIDED BY FINANCING ACTIVITIES	1,180,857	136,200	4,233,4
Net increase in cash and cash equivalents	629,886	2,021	1,600,0
Cash and cash equivalents at beginning of period	970,114	10,534	
Cash and cash equivalents at end of period	\$ 1,600,000	\$ 12,555	\$ 1,600,0

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Supplemental disclosure of cash flow information:

Cash paid during the period for:

Interest:	\$	--	\$	953	\$	41,8
		=====		=====		=====
Taxes:	\$	--	\$	--	\$	
		=====		=====		=====

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)  
Condensed Consolidated Statement of Cash Flows  
For the three months ended March 31, 2005 and  
2004, And for the period of inception (October 30, 2002)  
to March 31, 2005  
(Unaudited)

	For the Three Months Ended March 31, 2005	For the Three Months Ended March 31, 2004	Cumulati from Incept (October 2002) t March 31,
	-----	-----	-----
Non-cash investing and financing activities:			
Acquisition and capital restructure:	\$	\$	\$
Assets acquired	--	--	
Liabilities assumed	--	--	(120,7
Common stock retained	--	--	(2.3
Adjustment to additional paid-in capital	--	--	123,1
Organization costs	--	--	350,0
	-----	-----	-----
Total consideration paid	\$	\$	\$
	=====	=====	=====
Common stock issued in exchange for proprietary rights	\$	\$	\$
	=====	=====	=====
Common stock issued in exchange for services	\$	\$	\$
	=====	=====	=====
Common stock issued in exchange for previously incurred debt and accrued interest	\$	\$	\$
	=====	=====	=====

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Common stock issued in exchange as interest	\$ --	\$ 36,000	\$ 36,000
	=====	=====	=====
Amortization of beneficial conversion feature	\$ --	\$ 162,709	\$ 223,200
	=====	=====	=====
Stock options and warrants issued in exchange for services rendered	\$ 137,049	\$ 406,571	\$ 629,400
	=====	=====	=====
Debt and accrued interest forgiveness from note holders	\$ --	\$ 36,785	\$ 36,800
	=====	=====	=====
Common stock issued in satisfaction of accounts payable	\$ --	\$ 157,219	\$ 157,200
	=====	=====	=====
Common stock issued in satisfaction of amounts due to an Officer and a Director	\$ --	\$ 180,000	\$ 180,000
	=====	=====	=====
Deferred compensation to a consultant accrued in March 2005	\$ 32,500	\$ --	\$ 32,500
	=====	=====	=====

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IR BIOSCIENCES HOLDINGS, INC.  
(A DEVELOPMENT STAGE COMPANY)  
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
March 31, 2005

(Unaudited)

NOTE 1 - SUMMARY OF ACCOUNTING POLICIES

General

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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 periods ended March 31, 2005 and 2004 are not necessarily indicative of the results that may be expected for the years ended December 31, 2005. The unaudited condensed consolidated financial statements should be read in conjunction with the December 31, 2004 financial statements and footnotes thereto included in the Company's Securities and Exchange Commission Form 10-KSB.

Business and Basis of Presentation

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IR BioSciences Holdings, Inc. ("Company") formerly GPN Network, Inc. ("GPN") is currently a development stage company under the provisions of Statement of Financial Accounting Standards ("SFAS") No. 7. The Company, which was incorporated under the laws of the State of Delaware on October 30, 2002, is a biopharmaceutical company. Through our wholly owned subsidiary, ImmuneRegen BioSciences, Inc., we are engaged in the research and development of Homspera(TM), a proprietary compound that is derived from homeostatic substance P, a naturally occurring peptide. Currently, the majority of our development efforts are centered around a class of drug candidates derived from Homspera, Radilex(TM) and Viprovex(TM). Radilex has been formulated specifically for the indication of acute exposure to radiation. Viprovex was formulated specifically for applications relating to the treatment of various chemical agents, such as exposure to formalin, and biological agents, such as infectious disease and other Class A pathogens. Our research and development efforts are at a very early stage and Radilex and Viprovex have only undergone pre-clinical testing in mice. From its inception through the date of these financial statements, the Company has recognized no revenues and has incurred significant operating expenses.

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, ImmuneRegen BioSciences, Inc. Significant intercompany transactions have been eliminated in consolidation.

### 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

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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.

### Interim Financial Statements

-----

The accompanying balance sheet as of March 31, 2005, the statements of

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operations for the three months ended March 31, 2005 and 2004, and for the period of inception (October 30, 2002) to March 31, 2005, and the statements of cash flows for three months ended March 31, 2005 and 2004, and from the period of inception (October 30, 2002) to March 31, 2005 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.

### Long-lived Assets

-----

The Company accounts for its long-lived assets under the provision of Statements of Financial Accounting Standards No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets To Be Disposed Of." The Company's long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Events relating to recoverability may include significant unfavorable changes in business conditions, recurring losses, or a forecasted inability to achieve break-even operating results over an extended period. The Company evaluates the recoverability of long-lived assets based upon forecasted undiscounted cash flows. Should an impairment in value be indicated, the carrying value of intangible assets will be adjusted, based on estimates of future discounted cash flows resulting from the use and ultimate disposition of the asset.

### Prepaid Services and Other Current Assets

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Prepaid services and other current assets consist of (i) outside services that the Company has paid for in advance in the amount of \$2,525; (ii) salary advance to an employee of \$2,300; and (iii) deposits of \$2,260.

### Licensed Proprietary Rights

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The Company has licensed from its founders certain proprietary rights which the Company intends to utilize in the execution of its business plan. These proprietary rights are being amortized over the term of the license agreement, or ten years. The amount amortized during the three months ended March 31, 2005 and 2004 was \$232 during each period.

### 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

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as follows:

Computer equipment	3 years
Furniture	7 years

The amounts depreciated for the three months ended March 31, 2005 and 2004 were \$170 and 169, respectively. The amount depreciated from the date of inception (October 30, 2002) through March 31, 2005 was \$1,758.

### NOTE 2 - RELATED PARTY TRANSACTIONS

#### Proprietary Rights Agreement

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In December 2002, the Company entered into a royalty-free license agreement (the "License Agreement") with its two founders and largest shareholders (the "Licensors"). Under the terms of the License Agreement, the Licensors grant to the Company an exclusive license to use and sublicense certain patents, medical applications, and other technologies developed by the Licensors. The Company's obligations under the License Agreement include (i) reasonable efforts to protect any licensed patents or other associated property rights; (ii)

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reasonable efforts to maintain confidentiality of any proprietary information; (iii) upon the granting by the U. S. Food and Drug Administration to the Company the right to market a product, the Company will maintain a broad form general liability and product liability insurance.

#### Consulting Agreements

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On December 16, 2002, the Company entered into consulting agreements (the "Consulting Agreements") with its two founders and chief research scientists (the "Consultants"). The Consulting Agreements were on a month-to-month basis. Under the terms of the Consulting Agreements, the Consultants agreed to place at the disposal of the Company their judgment and expertise in the area of acute lung injury. In consideration for these services, the Company agreed to pay each consultant a non-refundable fee of \$5,000 per month, which shall accrue until such time as the Company raises at least \$2,000,000 in equity or debt financing at which time such accrued amount will become due and payable. Pursuant to the Consulting Agreements, during the period from January 1, 2003 to December 31, 2003, the Company accrued \$120,000 in consulting fees. During the period from January 1, 2004 to December 31, 2004, the Company accrued an additional \$90,000 in consulting fees. The amounts due the Consultants at December 31, 2003 was \$125,000 and was included in accounts payable and accrued expenses.

In October 2004, the Company achieved the threshold amount of \$2,000,000 in equity or debt financing (see Note I). As of October, 2004, the aggregate amounts due the Consultants under the Consulting Agreements were \$215,000.

In October, 2004, one of the Consultants elected to exchange 724,000 shares of the Company's common stock and a warrant to purchase an additional 362,000 (post-split) shares of common stock at an exercise price of \$0.50 (post-split) in exchange for \$90,500 of the \$107,500 of the previously accrued and unpaid fees due him under the Consulting Agreement, and the balance of \$17,000 was paid to the consultant. At December 31, 2004, there is no balance due to the Consultant.

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In October 2004, because the remaining Consultant had not taken an active role in the management of the Company, he agreed that would forgive the amount accrued to him under the Consulting agreement of \$107,500. The Company accounted for the transaction as a forgiveness of indebtedness under FAS No. 140 during the period ended December 31, 2004.

During the three months ended March 31, 2005 and 2004, the Company accrued \$19,000 and \$30,000, respectively, in consulting fees payable to the Company's founders.

### Employment Agreements

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Pursuant to our employment agreement with Michael Wilhelm, our President and Chief Executive Officer, dated December 16, 2002, we paid a salary of \$125,000 and \$175,000 to Mr. Wilhelm during the first and second years of his employment, respectively. Thereafter we paid, and will continue to pay, through the term of Mr. Wilhelm's employment, an annual salary of \$250,000. Mr. Wilhelm's salary is payable in regular installments in accordance with the customary payroll practices of our company.

Pursuant to our employment agreement with John Fermanis, our Chief Financial Officer, dated February 15, 2005, we paid a salary of \$60,000 until the company completed a financing of \$500,000 or more. This occurred on March 4, 2005 when the company completed a Tender Offer for warrants totaling \$1,190,857 net of fees. From March 4, 2005, until December 31, 2005, we will pay an annual salary of \$85,000. Thereafter, we will pay an annual salary of \$98,000 for the second year ending December 31, 2006 and an annual salary of \$112,000 for the third year ending December 31, 2007. Mr. Fermanis' salary is payable in regular installments in accordance with the customary payroll practices of our company.

### NOTE 3 - DEBT

During the three months ended March 31, 2005, the Company repaid a note payable in the amount of \$10,000. At March 31, 2005, the Company had outstanding two unsecured notes payable to Company shareholders in the aggregate amount of \$66,970. Interest accrues at 6% per annum. Accrued interest at March 31, 2005 is \$9,923. These notes were in default at March 31, 2005.

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### NOTE 4 - EQUITY

#### Common Stock

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On January 24, 2005, the Company made a tender offer to certain of the Company's shareholders whereby the exercise price of certain warrants issued in October 2004 (the "Warrants") would be reduced from \$0.50 to \$0.20 per share. In March 2005, 6,600,778 shares of common stock were sold pursuant to this offer for aggregate proceeds of \$1,320,156 less costs of \$129,300.

#### Warrants

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In January through March 2005, the Company issued warrants to purchase 268,033 shares at prices ranging from \$0.125 to \$1.00 to consultants for services performed. The Company valued these warrants using the Black-Scholes valuation model, and charged the amount of \$137,049 to operations during the three months



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ended March 31, 2005.

The following table summarizes the changes in warrants outstanding and the related prices for the shares of the Company's common stock issued to non-employees of the Company. These warrants were granted in lieu of cash compensation for services performed or financing expenses and in connection with placement of convertible debentures.

Warrants Outstanding		Warrants Exercisable			
Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighed Average Exercise Price	Number Exercisable	Weighted Remaining Contractual Life (Years)
\$0.05-0.10	480,698	4.35	\$0.05-0.10	480,698	4.35
0.125-0.70	782,411	4.21	0.125-0.70	782,411	4.21
0.25-0.56	9,147,932	4.31	0.25-0.56	9,147,932	4.31
1.00	754,844	2.73	1.00	754,844	2.73
2.00	167,580	4.27	2.00	167,580	4.27
	-----	-----		-----	-----
	11,333,465	4.20		11,333,465	4.20
	=====	=====		=====	=====

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Transactions involving warrants are summarized as follows:

	Number of Shares (post-split)	Weighted Average Price Per Share (post-split)
Outstanding at January 1, 2005	17,666,210	\$ .49
Granted	268,033	.48
Exercised	(6,600,778)	.50
Canceled or expired	--	--
	-----	-----
Outstanding at March 31, 2005	11,333,465	\$ .47
	=====	=====

The estimated value of the compensatory warrants granted to non-employees in exchange for services and financing expenses was determined using the Black-Scholes pricing model and the following assumptions:

	2005
Significant assumptions (weighted-average):	-----
Risk-free interest rate at grant date	3.75%
Expected stock price volatility	154% to 163%
Expected dividend payout	--
Expected option life-years (a)	3

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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-QSB 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-QSB.

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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IR BioSciences Holdings, Inc. is a development-stage biopharmaceutical company. Through our wholly owned subsidiary, ImmuneRegen BioSciences, Inc., we are engaged in the research and development of Homspera(TM), a proprietary compound that is derived from homeostatic substance P, a naturally occurring peptide. Currently, the majority of our efforts are focused on the research and development of potential uses of Radilex(TM), a compound derived from Homspera, as a possible therapeutic in response to toxic radiological or nuclear exposure. Our research and development efforts are at a very early stage and Radilex has only undergone pre-clinical testing in mice. We own or have obtained a license to 2 issued U.S. and 2 issued foreign patents and 5 pending Patent Cooperation Treaty (PCT) applications, 6 pending U.S. applications and 15 pending foreign patent applications.

### RESULTS OF OPERATIONS FOR THE THREE MONTH PERIOD ENDED MARCH 31, 2005

#### Revenue

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We are in the development stage and have no revenue.

#### Sales, General, and Administrative Expenses

-----

Sales, general, and administrative expenses ("SG&A") were \$838,520 for the three months ended March 31, 2005, an decrease of \$92,554 or approximately 10% compared to SG&A of \$931,074 during the three months ended

March 31, 2004. For the three months ended March 31, 2005, this amount consisted primarily of non-cash compensation issued to consultants of \$299,943, legal and accounting fees of \$161,806, other consulting fees of \$117,739, payroll and related costs of \$77,574, and research and development expenses of \$65,849.

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 \$977 for the three months ended March 31, 2005, a decrease of \$303,101 or approximately 99% compared to interest expense of \$304,078 for the three months ended March 31, 2004. Interest expense was dramatically reduced because the Company paid or converted to equity most of its outstanding debt during the three months ended December 31, 2004.

The Company expects interest expense to remain at low levels during the coming twelve months.

Net Loss

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For the reasons above, the net loss for the three months ended March 31, 2005 was \$839,497, a decrease of \$395,655 or 32% compared to a net loss of \$1,235,152 for the three months ended March 31, 2004.

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.

PLAN OF OPERATIONS

We expect to continue to incur increasing operating losses for the foreseeable future, primarily due to our continued research and development activities attributable to new and existing products and general and administrative activities.

Product Research and Development

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We spent approximately \$65,849 and \$21,382 for the first quarters ending March 31, 2005 and 2004, respectively, in research and development activities related to the development of Radilex as a universal protectant against the effects of chemical, biological, radiological and nuclear threats. Due to our liquidity and limited cash available, our spending on research and development activities was limited. From our inception in October 2002, we have spent \$258,912 in research and development activities. These costs include the manufacture and delivery of our drug by third party manufacturers, payments to Contract Research

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Organizations ("CRO") for consulting related to our studies and costs of performing such studies.

If we are successful in obtaining additional funding through grants or investment capital, we anticipate that during the next 12 months we will increase our research and development activities by approximately \$450,000 to a total of approximately \$600,000 in an effort to further develop Radilex and Viprovex, excluding a radiation study on primates which we estimate will cost \$1,500,000. If we are unable to raise additional capital, our research and development activities may be lessened. The drug development, clinical trial and regulatory process is lengthy, expensive and uncertain and subject to numerous risks.

Our major research and development projects include:

Research and development of Radilex.  
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We are currently preparing the protocols for our eighth mouse study in which we will further validate our prior studies by collecting additional data as requested by the FDA and NIH. We expect to begin the eighth study within the next 120 days. We estimate that the study will be completed within 3 months upon commencement at an estimated cost of \$100,000. Upon completion of the aforementioned study we will prepare the protocols necessary for a non-human primate study to test the efficacy of Radilex as a treatment to acute radiation sickness. We expect this study to begin within the next twelve months. We believe that preliminary results will be available within 90 days from beginning of study, with analysis within an additional 60 to 90 days. We have budgeted approximately \$100,000 for expenses related to this study in our fiscal year ending December 31, 2005. We expect an additional \$1,500,000 will be required to complete this study in 2006.

If we are successful in completing the study and achieve the desired results, we intend to submit the necessary documentation to the FDA and other regulatory agencies for approval. If approval for Radilex is granted, we expect to begin efforts to commercialize our product immediately thereafter. We are anticipating revenues from the sale of Radilex beginning in calendar year 2008 as a treatment to the effects caused by irradiation.

If product development or approval does not occur as scheduled our time to reach market will be lengthened and our costs will substantially increase. Additionally, we may be requested to expand our findings to gather additional data or we may not achieve the desired results. If so, we may have to design new protocols and conduct additional studies. This will increase our costs and delay the time to market for Radilex as a possible therapeutic for radiation exposure. Any of these occurrences would have a material negative impact on our business and our liquidity as it may cause us to seek additional capital sooner than expected and allow our competitors to successfully enter the market ahead of us.

RESEARCH AND DEVELOPMENT OF VIPROVEX IN CHEMICAL AND BIOLOGICAL EXPOSURE APPLICATIONS.  
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We are currently continuing to conduct preliminary research and development on the efficacy of Viprovex as a potential treatment for toxic chemical and biological exposure. Our initial testing has been limited to early preclinical studies on rodent models. We estimate approximately \$120,000 for additional studies related to the use of Viprovex in these areas over the next twelve months. We anticipate additional studies to begin in the fourth quarter of calendar 2005 and continue on an ongoing basis over the next three years. If we are successful in achieving desirable results, we intend to design the protocols and begin studies for these indications, when capital is available. As we have only collected preliminary data and additional studies are required, we cannot predict when, if ever, a viable treatment can be commercialized. If we do not observe significant results or we lack the capital to further the development, we may abandon such research and development efforts; thereby limiting our future potential revenues.

Research and development of Homspera in Wound Healing Applications.  
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Within the next six to nine months we plan to begin preclinical studies to determine if Homspera could become a compound that would be used in wound healing. We expect to begin studies in the fourth quarter of calendar 2005. We do not have any research and development expenses associated with the use of Homspera in wound healing in 2004 or 2003. We have budgeted approximately \$60,000 for the costs of such studies over the next twelve months. We anticipate the completion of such studies within eight months of commencement of the studies. If we achieve desirable results, we will design the protocols and begin studies for these indications, when capital is available. As we have only collected preliminary data and additional studies are required, we cannot predict when, if ever, a viable product can be commercialized. If we do not observe significant results or we lack the capital to further the development, we may abandon such research and development efforts; thereby limiting our future potential revenues.

We will need to generate significant revenues from product sales and or related royalties and license agreements to achieve and maintain profitability. Through March 31, 2005, we had no revenues from any product sales, royalties or licensing fees, and have not achieved profitability on a quarterly or annual basis. Our ability to achieve profitability depends upon, among other things, our ability to develop products, obtain regulatory approval for products under development and enter into agreements for product development, manufacturing and commercialization. Moreover, we may never achieve significant revenues or profitable operations from the sale of any of our products or technologies.

### OFF-BALANCE SHEET ARRANGEMENTS

There were no off-balance sheet arrangements made in the fiscal quarter ended March 31, 2005.

### REVENUES

We have not generated any revenues from operations from our inception. We believe we will begin earning revenues from operations during calendar year 2007 as we transition from a development stage company to that of an active growth and acquisition stage company.

### COSTS AND EXPENSES

From our inception through March 31, 2005, we have incurred losses of \$8,047,524. These expenses were associated principally with equity-based compensation to employees and consultants, product development costs and professional services.

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### LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2005, we had current assets of \$1,607,085 consisting of cash of \$1,600,000 and other current assets of \$7,085. At March 31, 2005, we also had current liabilities of \$408,180, consisting of accounts payable and accrued liabilities of \$341,210 and notes payable of \$66,970. This resulted in net working capital at March 31, 2005 of \$1,198,905. During the three months ended March 31, 2005, the Company used cash in operating activities of (\$550,971). From the date of inception (October 30, 2002) to March 31, 2005, the Company has had a net loss of (\$8,047,524) and has used cash of (\$2,625,316) in operating activities.

The Company currently has no revenue. There is no guarantee that our business model will be successful, or that we will be able to generate sufficient revenue to fund future operations. As a result, we expect our operations to continue to use net cash, and that we will be required to seek additional debt or equity financings during the coming quarters. Since inception, the Company has financed its operations through debt and equity financing. While we have raised capital to meet our working capital and financing needs in the past, additional financing is required in order to meet our current and projected cash flow deficits from operations and development of our product line. We met our cash requirements from our inception through March 31, 2005 via the private placement of \$3,259,903 of our common stock, \$973,500 from the issuance of notes payable, net of repayments and \$1,190,857, net of costs, from the exercise of common stock purchase warrants.

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In January 2005, we made a tender offer to temporarily reduce the exercise price of certain warrants issued in October 2004 from \$0.50 to \$0.20 per share. The tender offer expired on March 4, 2005. We accepted for exercise a total of 6,600,778 warrants validly tendered and not withdrawn pursuant to the terms of the tender offer, which represents approximately 48% of the aggregate 13,780,449 warrants that were subject to the offer. We raised an aggregate of \$1,190,857 from the tender offer, net of costs.

Since our inception, we have been seeking additional third-party funding. During such time, we have retained a number of different investment banking firms to assist us in locating available funding; however, we have not yet been successful in obtaining any of the long-term funding needed to make us into a commercially viable entity. During the period from October 2004 to March 2005, we were able to obtain financing of \$3,770,156 from a series of private placements of our securities. Included in this amount was the conversion of \$180,000 of accrued salary and consulting fees due to an officer and a director of the company. These private placements of our securities resulted in net proceeds to us of \$3,162,711. Based on our current plan of operations all of our current funding is expected to be depleted by the end of January 2006. Although we are continuing with our efforts to obtain funding to maintain our operations, we cannot assure you that we will be successful or that any funding we receive will be received timely or on commercially reasonable terms. Due to our working capital deficiency, and if we do not receive adequate financing, we will be unable to pay our vendors, lenders and other creditors if we cease our operations, since the net realizable value of our non-current assets will not generate adequate cash. We currently have no commitments for financing. There is no guarantee that we will be successful in raising the funds required.

In the event that we are successful in obtaining third-party funding, we do not expect to generate a positive cash flow from our operations for at least several years, if at all, due to anticipated expenditures for research and development

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activities, administrative and marketing activities, and working capital requirements and expect to continue to attempt to raise further capital through one or more further private placements.

While we have successfully raised capital to meet our working capital and financing needs in the past through debt and equity financings, additional financing will be required in order to implement our business plan and to meet our current and projected cash flow deficits from operations and development. There can be 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. If we are unable to raise needed funds, we will not be able to develop or enhance our products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets or seeking an acquisition partner. We believe that we have sufficient capital resources to meet projected cash flow deficits through the end of December 2005. However, if thereafter, we are not successful in generating sufficient liquidity from operations or in raising sufficient capital resources, this would have a material adverse effect on our business, results of operations, liquidity and financial condition.

During the three months ended March 31, 2005, the Company paid a note payable in the amount of \$10,000. At March 31, 2005, the Company had outstanding two unsecured notes payable to Company shareholders in the aggregate amount of \$66,970. Interest accrues at 6% per annum. Accrued interest at March 31, 2005 is \$9,923. These notes were in default at March 31, 2005.

Pursuant to our employment agreement with Michael Wilhelm, our President and Chief Executive Officer, dated December 16, 2002, we paid a salary of \$125,000 and \$175,000 to Mr. Wilhelm during the first and second years of his employment, respectively. Thereafter we paid, and will continue to pay, through the term of Mr. Wilhelm's employment, an annual salary of \$250,000. Mr. Wilhelm's salary is payable in regular installments in accordance with the customary payroll practices of our company.

Pursuant to our employment agreement with John Fermanis, our Chief Financial Officer, dated February 15, 2005, we paid a salary of \$60,000 until the company completed a financing of \$500,000 or more. This occurred on March 4, 2005 when the company completed a Tender Offer for warrants totaling \$1,190,856 net of fees. From March 4, 2005, until December 31, 2005, we will pay an annual salary of \$85,000. Thereafter, we will pay an annual salary of \$98,000 for the second year ending December 31, 2006 and an annual salary of \$112,000 for the third year ending December 31, 2007. Mr. Fermanis' salary is payable in regular installments in accordance with the customary payroll practices of our company.

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On December 16, 2002 we entered into a consulting agreement on a month-to-month basis with Dr. Mark Witten, our chief research scientist and director. Under the terms of this agreement, Dr. Witten agrees to place at the disposal of us his judgment and expertise in the area of acute lung injury. In consideration for these services, we agree to pay Dr. Witten a non-refundable fee of \$5,000 per month. Under the terms of our consulting agreement with Dr. Mark Witten, he is to receive a non-refundable fee equal to \$5,000 per month. The consulting agreement is on a month-to-month basis.

### Acquisition or Disposition of Plant and Equipment

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We did not dispose or acquire any significant property, plant or equipment

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during the first quarter ended March 31, 2005.

We do not anticipate the sale of any significant property, plant or equipment during the next twelve months.

Number of Employees

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From our inception through the period ended March 31, 2005, we have relied on the services of outside consultants for services and currently have five total employees, two contract employees and three full-time employees. In order for us to attract and retain quality personnel, we anticipate we will have to offer competitive salaries to future employees. We do not anticipate our employment base will significantly change during the next twelve months, other than the addition of one senior level appointment to the position of Senior Vice President of Scientific Development. As we continue to expand, we will incur additional cost for personnel. This projected increase in personnel is dependent upon our generating revenues and obtaining 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.

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.

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

We have incurred a substantial net loss for the period from our inception in October 2002 to March 31, 2005, and are currently experiencing negative cash flow. We expect to continue to experience negative cash flow and operating losses through at least 2008 and possibly thereafter. As a result, we will need to generate significant revenues to achieve profitability.

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

We are focused on product development and have not generated any revenue to date. We have incurred operating losses since our inception. Our net loss for fiscal year 2004 was \$(5,305,407). As of March 31, 2005, we had an accumulated deficit of \$ (8,047,524).

We currently have no product candidates for sale in the United States, and we cannot guarantee that we will ever have marketable products in the United States. We must demonstrate that our product candidates satisfy rigorous



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standards of safety and efficacy before the U.S. Food and Drug Administration ("FDA") and other regulatory authorities in the United States and abroad will approve the products for commercial marketing. We will need to conduct significant additional research, preclinical testing and clinical testing before we can file applications with the FDA for approval of our product candidates. In addition, to compete effectively, our future products must be easy to use, cost-effective and economical to manufacture on a commercial scale. We may not achieve any of these objectives.

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

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

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

IF OUR PLAN IS NOT SUCCESSFUL OR MANAGEMENT IS NOT EFFECTIVE, THE VALUE OF OUR COMMON STOCK MAY DECLINE.

Our operating subsidiary, ImmuneRegen BioSciences, Inc., was founded in October 2002. As a result, we are a development stage company with a limited operating history that makes it impossible to reliably predict future growth and operating results. Our business and prospects must be considered in light of the risks and uncertainties frequently encountered by companies in their early stages of development. In particular, we have not demonstrated that we can:

- o ensure that our products function as intended in human clinical applications;
- o obtain the regulatory approvals necessary to commercialize products that we may develop in the future;
- o manufacture, or arrange for third-parties to manufacture, future products in a manner that will enable us to be profitable;
- o establish many of the business functions necessary to operate, including sales, marketing, administrative and financial functions, and establish appropriate financial controls;

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- o make, use, and sell future products without infringing upon third party intellectual property rights; or
- o respond effectively to competitive pressures.

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

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

As of March 31, 2005, our cash and cash equivalents totaled approximately \$1,600,000. Based on our current plans, we believe these financial resources, and interest earned thereon, will be sufficient to meet our operating expenses and capital requirements at least through December 31, 2005. However, changes in our research and development plans or other events affecting our operating expenses may result in the expenditure of such cash before that time. We may require substantial additional funds in order to finance our drug discovery and development programs, fund operating expenses, pursue regulatory clearances, develop manufacturing, marketing and sales capabilities, and prosecute and defend our intellectual property rights. We may seek additional funding through public or private financing or through collaborative arrangements with strategic partners.

You should be aware that in the future:

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

If we cannot raise additional funds when needed, or on acceptable terms, we will not be able to continue to develop our drug candidates. We require substantial working capital to fund our operations. Since we do not expect to generate significant revenues in the foreseeable future, in order to fund operations, we will be completely dependent on additional debt and equity financing arrangements. There is no assurance that any financing will be sufficient to fund our capital expenditures, working capital and other cash requirements beyond December 31, 2005. Our working capital as of March 31, 2005 was \$ 1,198,905. No assurance can be given that any such additional funding will be available or that, if available, can be obtained on terms favorable to us. If we are unable to raise needed funds on acceptable terms, we will not be able to develop or enhance our products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. A material shortage of capital will require us to take drastic steps such as reducing our level of operations, disposing of selected assets or seeking an acquisition partner. If cash is insufficient, we will not be able to continue operations.

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

All our potential applications are derived from the use of Homspera. In

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addition, we expect to utilize Homspera in the development of any future products we market. If these current or future Homspera-based products are found to be unsafe or ineffective due to the use of Homspera, we may have to modify or cease production of the products. As all of our applications utilize or will utilize Homspera, any findings that Homspera is unsafe or ineffective would severely harm our Homspera-based business operations, since all of our primary revenue sources would be negatively affected by such findings. In such an event, we may be required to cease operations.

We will need to conduct significant additional research, preclinical testing and clinical testing before we can file applications with the FDA for approval of our product candidates.

To date we have not yet made applications with the FDA or any other governmental regulatory agency for approval for our product candidates. Until such as time as our New Drug Application (NDA) is filed and subsequently approved, we will not be able to manufacture products.

Our research and preclinical testing is currently directed in developing products candidates based on our proprietary compound, Homspera. We have demonstrated in early preclinical studies evidence that may suggest that Homspera may be used to treat the suppression of the body's immune system caused by exposure to various forms of radiation, toxic inhalants and viral infectious diseases. As a research and development company, we may, from time to time, pursue the development of other products based on discoveries made during our studies. To differentiate from these other potential future applications, we are developing specific candidates under the name Radilex as a potential treatment for maladies caused by exposure to various forms of radiation, and Viprovex, as a potential treatment to various toxic inhalants and viral infectious diseases.

We are currently conducting formulation, toxicity and stability studies on Homspera, Radilex and Viprovex. We anticipate that these studies will be completed in 12 to 15 months.

Also in conjunction with these studies, we plan to begin a rodent study using Radilex. We expect the study to be completed within 12 to 15 months. In parallel with the rodent study, we intend to begin our preparations for the filing of an Investigational New Drug Application (IND). We expect the IND to be filed with the FDA within the next 16 to 18 months. At the conclusion of the rodent study, we anticipate commencing a study in non-human primates. We expect this study to be completed within 20 to 24 months. Based on positive study results, we expect to file a New Drug Application (NDA) with the FDA within the next 36 months.

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

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

Our therapies and technologies utilizing Radilex and Viprovex are at early stages of development and may not be shown to be safe or effective and may never receive regulatory approval. Our technologies utilizing Radilex, Viprovex and

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Homspera have not yet been tested in humans. Regulatory authorities may not permit human testing of potential products based on these technologies. Even if human testing is permitted, any potential products based on Homspera may not be successfully developed or shown to be safe or effective.

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

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

THE MARKET FOR TREATING ACUTE RADIATION SYNDROME (ARS) AND EXPOSURE TO VARIOUS BIOLOGICAL AGENTS IS UNCERTAIN IF WE ARE UNABLE TO SUCCESSFULLY COMMERCIALIZE RADILEX OR VIPROVEX, WE WILL NOT RECOGNIZE A SIGNIFICANT PORTION OF OUR PLANNED REVENUES.

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

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

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THE LENGTHY PRODUCT APPROVAL PROCESS AND UNCERTAINTY OF GOVERNMENT REGULATORY REQUIREMENTS MAY DELAY OR PREVENT US FROM COMMERCIALIZING PROPOSED PRODUCTS, AND THEREFORE ADVERSELY AFFECT THE TIMING AND LEVEL OF FUTURE REVENUES, IF ANY.

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

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

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

- o labeling and advertising requirements, restrictions or limitations, including the inclusion of warnings, precautions, contra-indications or use limitations that could have a material impact on the future profitability of our applications;
- o testing and surveillance to monitor our future products and their continued compliance with regulatory requirements;
- o submitting products for inspection and, if any inspection reveals that the product is not in compliance, prohibiting the sale of all products;
- o suspending manufacturing; or
- o withdrawing marketing clearance.

Additionally, the FDA's policies may change and additional government regulations may be enacted, which could prevent or delay regulatory approval of our applications. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market our future products and our business could suffer. Even if human clinical trials of Radilex, Viprovex and Homspera are initiated and successfully completed, the FDA may not approve Radilex, Viprovex and Homspera for commercial sale. We may encounter significant delays or excessive costs in our efforts to secure necessary approvals. Regulatory requirements are evolving and uncertain. Future United States or foreign legislative or administrative acts could also prevent or delay regulatory approval of our products. We may not be able to obtain the necessary approvals for clinical trials, manufacturing or marketing of any of our products

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under development. Even if commercial regulatory approvals are obtained, they may include significant limitations on the indicated uses for which a product may be marketed.

The FDA has not designated expanded access protocols for Radilex, Viprovex and Homspera as "treatment" protocols. The FDA may not determine that Radilex, Viprovex and Homspera meet all of the FDA's criteria for use of an investigational drug for treatment use. Even if Radilex, Viprovex and Homspera are allowed for treatment use, third party payers may not provide reimbursement for the costs of treatment with Radilex, Viprovex and Homspera. The FDA also may not consider Radilex, Viprovex and Homspera to be an appropriate candidate for accelerated approval, expedited review or fast track designation.

IF WE FAIL TO OBTAIN APPROVAL FROM FOREIGN REGULATORY AUTHORITIES, WE WILL NOT BE ALLOWED TO MARKET OR SELL OUR PRODUCTS IN OTHER COUNTRIES, WHICH WOULD ADVERSELY AFFECT OUR LEVELS OF FUTURE REVENUES, IF ANY.

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

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

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

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

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

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completing clinical trials for our applications, or in receiving regulatory approval for the sale of any products resulting from our applications, may severely harm our business and reputation.

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

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

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

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

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

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

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

We also rely on our manufacturers to supply us with a sufficient quantity of our drug candidates to conduct clinical trials. If we have difficulty in the future

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obtaining our required quantity and quality of supply, we could experience significant delays in our development programs and regulatory process.

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

The manufacturing process of our proposed products is expected to involve a number of steps and requires compliance with stringent quality control specifications imposed by us and by the FDA. We have no experience in the sales, marketing and distribution of pharmaceutical or biotechnology products. We have not manufactured any of our products in commercial quantities. We may not

successfully arrange for contract manufacturing of our products in production quantities and this could prevent us from commercializing products or limit our profitability from our products.

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

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

For the manufacture of the applications under development, we obtain synthetic peptides from third party manufacturers. A synthesized version of 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. If any of these proposed manufacturing operations prove inadequate, there may be no assurance that any other arrangements may be established on a timely basis or that we could establish other manufacturing capacity on a timely basis. Although, we believe that the synthetic substance P and other materials necessary to produce Radilex,

Viprovex and Homspere are readily available from various sources, and several suppliers are capable of supplying substance P in both clinical and commercial quantities, our dependence on such manufacturers, may delay or impair our ability to generate revenues, or adversely affect our profitability.

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



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

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

Our ability to market and commercialize Radilex, Viprovex and Homspera depends on the acceptance and utilization of Homspera by the medical community. We will need to develop commercialization initiatives designed to increase awareness about us and Homspera among targeted audiences, including public health activists and community-based outreach groups in addition to the investment community. Currently, we have not developed any such initiatives. Without such acceptance of Homspera, the product upon which we expect to be substantially dependent, we may not be able to successfully commercialize Homspera or generate revenue.

PRODUCT LIABILITY EXPOSURE MAY EXPOSE US TO SIGNIFICANT LIABILITY OR COSTS, WHICH WOULD ADVERSELY IMPART OUR FUTURE OPERATING RESULTS AND DIVERT FUNDS FROM THE OPERATION OF OUR BUSINESS.

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

WE MAY FAIL TO PROTECT ADEQUATELY OUR PROPRIETARY TECHNOLOGY, WHICH WOULD ALLOW COMPETITORS TO TAKE ADVANTAGE OF OUR RESEARCH AND DEVELOPMENT EFFORTS, THE EFFECT OF WHICH COULD ADVERSELY AFFECT ANY COMPETITIVE ADVANTAGE WE MAY HAVE.

We own or have obtained a license to 4 issued U.S. and foreign patents and 24 pending U.S. and foreign patent applications. Our success will depend in part on our ability to obtain additional United States and foreign patent protection for our drug candidates and processes, preserve our trade secrets and operate without infringing the proprietary rights of third parties. We place considerable importance on obtaining patent protection for significant new technologies, products and processes.

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

Legal standards relating to the validity of patents covering pharmaceutical and biotechnology inventions and the scope of claims made under such patents are still developing. In some of the countries in which we intend to market our products, pharmaceuticals are either not patentable or have only recently become patentable. Past enforcement of intellectual property rights in many of these countries has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries may be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions. The U.S. Patent and Trademark Office, commonly referred to as the USPTO, and the courts have not consistently treated the breadth of claims allowed in biotechnology patents. If the USPTO or the courts begin to allow broader claims, the incidence and cost of patent interference proceedings and the risk of infringement litigation will likely increase. On the other hand, if the USPTO or the courts begin to allow narrower claims, the value of our proprietary rights may be limited. Any changes in, or unexpected interpretations of the patent laws may adversely affect our ability to enforce our patent position.

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

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

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### PRODUCTS.

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

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

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

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

If our products violate third-party proprietary rights, we cannot assure you that we would be able to arrange licensing agreements or other satisfactory resolutions on commercially reasonable terms, if at all. Any claims made against us relating to the infringement of third-party proprietary rights could result in the expenditure of significant financial and managerial resources and injunctions preventing us from providing services. Such claims could severely harm our financial condition and ability to compete. In addition, if another party claims the same subject matter or subject matter overlapping with the subject matter that we have claimed in a United States patent application or patent, we may decide or be required to participate in interference proceedings in the United States Patent and Trademark Office in order to determine the priority of invention. Loss of such an interference proceeding would deprive us of patent protection sought or previously obtained and could prevent us from commercializing our products. Participation in such proceedings could result in substantial costs, whether or not the eventual outcome is favorable. These additional costs could adversely affect our financial results.

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

We may be required to incur significant costs to comply with current or future

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environmental laws and regulations. Although we do not currently manufacture commercial quantities of our proposed products, we do produce limited

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quantities of these products for our clinical trials. Our research and development and manufacturing processes involve the controlled storage, use and disposal of hazardous materials, biological hazardous materials and radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and some waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, the risk of contamination or injury from these materials cannot be completely eliminated. In the event of an

incident, IR BioSciences Holdings, Inc. or ImmuneRegen BioSciences, Inc. could be held liable for any damages that result, and any liability could exceed our resources. Current or future environmental laws or regulations may have a material adverse effect on our operations, business and assets.

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

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

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

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

TRADING IN OUR SECURITIES COULD BE SUBJECT TO EXTREME PRICE FLUCTUATIONS THAT COULD ADVERSELY AFFECT THE PRICE OF OUR COMMON STOCK AND THUS ADVERSELY AFFECT THE VALUE OF ANY INVESTMENT IN OUR COMMON STOCK.

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

- o biological or medical discoveries by competitors;

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- o public concern about the safety of our drug candidates;
- o delays in the conduct or analysis of our preclinical or clinical studies;
- o unfavorable results from preclinical or clinical studies;

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- o unfavorable developments concerning patents or other proprietary rights; or
- o unfavorable domestic or foreign regulatory developments;

may have the effect of temporarily or permanently driving down the price of our common stock. In addition, the stock market from time to time experiences extreme price and volume fluctuations which particularly affect the market prices for emerging and life sciences companies, such as ours, and which are often unrelated to the operating performance of the affected companies. For example, our stock price has ranged from \$0.09 to \$1.00 between January 1, 2004 and April 3, 2005.

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

A LIMITED PRIOR PUBLIC MARKET AND TRADING MARKET MAY CAUSE VOLATILITY IN THE PRICE OF OUR COMMON STOCK.

Our common stock is currently traded on a limited basis on the OTC Bulletin Board (the "OTCBB") under the symbol "IRBO". The OTCBB is an inter-dealer, Over-The-Counter market that provides significantly less liquidity than the NASDAQ Stock Market. Quotes for stocks included on the OTCBB are not listed in the financial sections of newspapers as are those for the NASDAQ Stock Market. Therefore, prices for securities traded solely on the OTCBB may be difficult to obtain and holders of common stock may be unable to resell their securities at or near their original offering price or at any price.

The NASD has enacted recent changes that limit quotations on the OTC Bulletin Board to securities of issuers that are current in their reports filed with the Securities and Exchange Commission. The effect on the OTC Bulletin Board of these rule changes and other proposed changes cannot be determined at this time.

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

SALES OR ISSUANCES OF ADDITIONAL EQUITY SECURITIES MAY ADVERSELY AFFECT THE

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MARKET PRICE OF OUR COMMON STOCK AND YOUR RIGHTS IN US MAY BE REDUCED.

Certain of our stockholders have the right to register securities for resale that they hold pursuant to registration rights agreements. We expect to continue to incur product development and selling, general and administrative costs, and in order to satisfy our funding requirements, we will need to sell additional equity securities, which may be subject to similar registration rights. The sale or the proposed sale of substantial amounts of our common stock in the public markets may adversely affect the market price of our common stock. We expect that an aggregate of 52,391,374 shares of our

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common stock will be registered with the SEC in the registration statement. The registration and subsequent sales of such shares of common stock may have an adverse effect on the market price of our common stock.

From time to time, certain stockholders of our company may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Act ("Rule 144"), subject to certain limitations. In general, pursuant to Rule 144, a stockholder (or stockholders whose shares are aggregated) who has satisfied a one-year holding periods may, under certain circumstances, sell within any three-month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of our common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale. Rule 144 also permits, under certain circumstances, the sale of securities, without any limitations, by a non-affiliate of our company who has satisfied a two-year holding period. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have an adverse effect on the market price of our securities.

Our stockholders may experience substantial dilution and a reduction in the price that they are able to obtain upon sale of their shares. Also, any new equity securities issued, including any new series of preferred stock authorized by our board of directors, may have greater rights, preferences or privileges than our existing common stock. To the extent stock is issued or options and warrants are exercised, holders of our common stock will experience further dilution. In addition, as in the case of the warrants, in the event that any future financing should be in the form of, be convertible into or exchangeable for, equity securities and upon the exercise of options and warrants, security holders may experience additional dilution.

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## PART II - OTHER INFORMATION

### ITEM 6. EXHIBITS

#### (a) Exhibits

- 31.1 Certification of Chief Executive Officer pursuant to Item 601(b)(31) of Regulation S-B, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

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- 31.2 Certification of Chief Financial Officer pursuant to Item 601(b) (31) of Regulation S-B, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certifications of Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*

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- 32.2 Certifications of Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on November 16, 2005.

IR BioSciences Holdings, Inc.

By: /s/ Michael K. Wilhelm

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Michael K. Wilhelm  
President, Chief Executive Officer

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