IR BIOSCIENCES HOLDINGS INC Form 10-O

November 16, 2009

#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2009

or

oTransition 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.)

8777 E. Via De Ventura, Suite 280,

Scottsdale, AZ

(Address of Principal Executive Offices) (Zip Code)

\_\_\_\_\_N/A\_\_\_\_\_

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

85258

(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 o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T

(§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer " Accelerated filer " Non-accelerated filer " (Do not check if a smaller reporting company) Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

The number of shares outstanding of Registrant's common stock as of November 11, 2009 was 13,297,525.

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#### ITEM 1. FINANCIAL INFORMATION

# IR BioSciences Holdings, Inc. and Subsidiary (A Development Stage Company) Condensed Consolidated Balance Sheets as of September 30, 2009 (unaudited) And December 31, 2008

Assets Current assets		September 30, 2009 unaudited)	]	December 31, 2008
Cash and cash equivalents	\$	786,834	\$	3,158,226
Prepaid services and other current assets (note 1)	Ψ	82,162	Ψ	222,018
· · · · · · · · · · · · · · · · · · ·		- , -		,
Total current assets		868,996		3,380,244
Deposits and other assets (note 1)		7,693		7,378
Furniture and equipment, net of accumulated depreciation of				
\$86,417 and \$75,480, respectively (note 2)		31,910		41,347
Tracel accords	d.	000 500	ф	2 420 060
Total assets	\$	908,599	\$	3,428,969
Liabilities and Stockholders' Deficit				
Current liabilities				
Accounts payable and accrued liabilities (note 3)	\$	728,366	\$	862,926
Current portion of notes payable (note 4)	φ	1,500,000	Ψ	1,500,000
Redemption option liability		225,000		1,500,000
Redemption option natinty		223,000		_
Total current liabilities		2,453,366		2,362,926
Total carrent nationales		2,133,300		2,302,720
Derivative liability (Note 5)		4,170,881		_
Notes payable, net of discount of \$3,165,709 and \$1,474,937, respectively (note 4)		4,203,180		5,293,952
1,0000 payments, new or unsecount or 40,200,700 unit 41,777, 1,501, 120pcourterly (11000-17)		.,200,100		0,200,002
Total liabilities		10,827,427		7,656,878
		, ,		, ,
Commitments and contingencies		-		-
Stockholders' deficit (Note 6)				
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; 13,297,525 shares				
and 12,264,191 shares issued and outstanding at September 30, 2009 and December				
31, 2008, respectively		13,298		12,265
Additional paid-in capital		18,542,872		20,066,317

Common stock subscribed (Note 6)		16,000		250,000
Deficit Accumulated during the development stage	(2	28,490,998)	(	24,556,491)
Total stockholder's deficit		(9,918,828)		(4,227,909)
Total liabilities and stockholder's deficit	\$	908,599	\$	3,428,969

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

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IR BioSciences Holdings, Inc. and Subsidiary

(A Development Stage Company)

Condensed Consolidated Statements of Losses
for the three and nine months ended September 30, 2009 and 2008,
and for the period of inception (October 30, 2002) to September 30, 2009

(Unaudited)

		For the Three Months Ended September 30,				or the Nine N Septem			For the Period October 30, 2002 to September	
	<b>.</b>	2009	Φ.	2008	<b>.</b>	2009	Φ.	2008	Φ.	30, 2009
Revenues	\$	-	\$	-	\$	-	\$	-	\$	-
Operating expenses:										
1 2 1										
Selling, general and administrative										
expenses		743,383		1,776,708		2,408,251		3,671,252		23,518,205
Merger fees and costs		-		-		-		-		350,000
Impairment of intangible asset costs		-		-		-		-		6,393
Total operating expenses		743,383		1,776,708		2,408,251		3,671,252		23,874,598
Operating loss		(743,383)		(1,776,708)		(2,408,251)		(3,671,252)		(23,874,598)
Operating 1055		(743,303)		(1,770,700)		(2,400,231)		(3,071,232)		(23,074,370)
Other expense:										
Cost of penalty for late registration of										
shares		-		-		-		-		2,192,160
(Gain) loss from marking to market -										
warrant portion of penalty for late										
registration of shares		-		-		-		-		(378,198)
(Gain) loss from marketing to market -										
stock portion of penalty for late										(7(0,050)
registration of shares		-		-		-		-		(760,058)
(Gain) loss from change in fair value of derivative liability		1,706,401				3,082,961				(490,004)
Financing cost		31,250		31,250		93,750		148,125		363,125
Interest (income) expense, net		543,122		205,805		1,608,880		310,280		3,678,831
interest (income) expense, net		JTJ,122		203,003		1,000,000		310,200		3,076,631
Total other (income) expense		2,280,773		237,055		4,785,591		458,405		4,605,856
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Income (loss) before income taxes		(3,024,156)		(2,013,763)		(7,193,842)		(4,129,657)	(	(28,480,454)
Provision for income taxes		-		-		-		-		(10,544)
NT-4 (I)	ф	(2.024.150)		(2.012.7(2)		(7.102.040)		(4.100.657)	ф	(20, 400, 000)
Net (loss)	\$	(3,024,156)		(2,013,763)		(7,193,842)		(4,129,657)	\$	(28,490,998)
Net (loss) per share - basic and diluted	\$	(0.23)	\$	(0.17)	\$	(0.55)	\$	(0.35)	\$	(3.74)
( ) 1		()		( /)		()		()		( )

Weighted average shares outstanding -

basic and diluted 13,201,148 11,935,282 13,114,131 11,675,701 7,621,046

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

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	Common Shares	Stock Amount	Additional Paid-In Capital	Deferred Compensation	Common Stock Subscribed	Accumulated Deficit	Total
Balance at October 30, 2002 (date of inception)	-	\$ -	-		\$ -		\$ -
Shares of common stock issued at \$0.006 per share to founders for license of proprietary right in December 2002	1,661,228	1,661	7,589	) _	_	_	9,250
Shares of common stock issued at \$0.006 per share to founders for services rendered in December 2002	140,531	141	641	_	-	-	782
Shares of common stock issued at \$1.671 per share to consultants for services rendered in December 2002	5,388	5	8,995	5 (9,000)	_	_	_
	18,558	19	30,982	2 -	-	-	31,001

Sale of							
common stock							
for cash at							
\$1.671 per							
share in							
December							
2002							
Net loss for the							
period from							
inception							
(October 30,							
2002) to							
December 31,							
2002	-	-	-	-		(45,918)	(45,918)
Balance at							
December 31,							
2002							
(reflective of							
stock splits)	1,825,704	\$ 1,826	\$ 48,207	\$ (9,000) \$	- \$	(45,918) \$	(4,885)

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

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	Common Shares	Stock Amount	Additional Paid-In Capital	Deferred Compensation	Common Stock Subscribed	Accumulated Deficit	Total
Shares granted to consultants at \$1.392 per share for services rendered in January 2003	9,878	10	13,740	_	_	_	13,750
Sale of shares of common stock for cash at \$1.517 per share in January 2003	32,955	33	49,967	-	-	-	50,000
Shares granted to consultants at \$1.392 per share for services rendered in March 2003	15,445	15	21,485	_	_	_	21,500
Conversion of notes payable to common stock at \$1.392 per share in April 2003	143,674	144	199,856	-	-	-	200,000
Shares granted to consultants at \$1.413 per share for services rendered in April 2003	1,437	1	2,029	-	_	-	2,030
Sale of shares of common stock for cash at \$2.784 per share in May 2003	1,796	2	4,998	_	_	_	5,000

Sales of shares of common stock for cash at \$2.784 per share in June 2003	3,592	4	9,996	<u>-</u>	-	<u>-</u>	10,000
Conversion of notes payable to common stock at \$1.392 per share in June 2003	71,837	72	99,928	<u>-</u>	_	_	100,000
Beneficial conversion feature associated with notes issued	,	·					
in June 2003	-	-	60,560	-	-	-	60,560
Amortization of deferred compensation	-	_	-	9,000	-	-	9,000
Costs of GPN Merger in July 2003	236,813	237	(121,036)	-	-	-	(120,799)
Value of warrants issued with extended notes payable in October 2003	<u>-</u>	-	189,937	<u>-</u>	-	-	189,937
Value of Company warrants issued in conjunction with fourth quarter notes payable issued October through			207.457				207.457
December 2003	-	-	207,457	-	-	-	207,457
Value of warrants contributed by founders in conjunction with fourth quarter notes payable issued October through	<del>-</del>	-	183,543	<del>-</del>	-	-	183,543

December 2003								
Value of warrants								
issued for								
services in								
October through								
December 2003	-	-	85,861	-		-	-	85,861
Net loss for the								
twelve month								
period ended								
December 31,								
2003	-	-	-	-		-	(1,856,702)	(1,856,702)
								-
Balance at								
December 31,								
2003	2,343,130	\$ 2,343	\$ 1,056,529	\$ -	\$	-	\$ (1,902,620)	\$ (843,748)

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

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	Common Shares	Stock Amount	Additional Paid-In Capital	Deferred Compensation	Common Stock Subscribed	Accumulated Deficit	Total
Shares granted at \$10.00 per share pursuant to the Senior Note Agreement in January 2004	60,000	60	599,940	(600,000)	_	_	_
Shares issued at \$10.00 per share to a consultant for services rendered in January 2004	80,000	80	799,920	(800,000)	-	-	-
Shares issued to a consultant at \$6.20 per share for services rendered in February 2004	4,000	4	24,796	(24,800)	-	_	-
Shares issued to a consultant at \$4.00 per share for services rendered in March 2004	105,160	105	420,535	(420,640)	-	_	_
Shares issued to a consultant at \$5.00 per share for services rendered in March 2004	50,000	50	249,950	(250,000)	-	_	-
Shares sold for cash at \$1.50 per share in March, 2004	800	1	1,199	-	-	-	1,200

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Shares issued at \$5.00 per share to consultants for services rendered in March 2004	2,000	2	9,998	-	-	_	10,000
Shares issued to a consultant at \$4.00 per share for services rendered in March 2004	200	0	800	<u>-</u>	-	_	800
Shares issued to consultants at \$3.20 per share for services rendered in March 2004	9,160	9	29,303	_	_	_	29,312
Shares to be issued to consultant at \$4.10 per share in April 2004 for services to be rendered through March 2005	_	<u>-</u>	_	(82,000)	_	_	(82,000)
Shares granted pursuant to the New Senior Note Agreement in April 2004	60,000	60	149,940	(150,000)	_	_	_
Shares issued to officer at \$3.20 per share for services rendered in April 2004	20,000	20	63,980	-	-	-	64,000
Conversion of Note Payable to common stock at \$1.00 per share in May 2004	35,000	35	34,965	-	-	_	35,000

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	Common Shares	Stock Amount	Additional Paid-In Capital	Deferred Compensation	Common Stock Subscribed	Accumulated Deficit	Total
Beneficial Conversion Feature associated with note payable in May 2004	-	-	35,000	-	-	-	35,000
Issuance of warrants to officers and founder for services rendered in May 2004	_		269,208	_	_	_	269,208
III Way 2004			207,200				207,200
Shares to a consultant at \$2.00 per share as a due diligence fee in May 2004	12,500	13	24,988	_	_	-	25,000
Shares issued to a consultant at \$10.00 per share for services to be rendered over twelve months beginning May 2004	50,000	50	499,950	(500,000)	_	_	_
Beneficial Conversion Feature associated with notes payable issued in June 2004	_	_	3,000	<u>-</u>	_	_	3,000
Issuance of warrants to note holders in April,	-	-	17,915	-	-	-	17,915

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May, and June 2004							
Issuance of warrants to employees and consultants for services rendered in April through June 2004	_	-	8,318	_	-	_	8,318
Shares issued in July to a consultant at \$1.00 for services to be rendered through July 2005	25,000	25	24,975	(25,000)	_	_	_
Shares issued to a consultant in July and September at \$4.10 per share for services to be rendered through April 2005	20,000	20	81,980	_	_	_	82,000
Shares issued to a consultant in September at \$1.20 to \$2.20 for services rendered through September 2004	12,728	13	16,896	_	_	_	16,909
Shares issued in July to September 2004 as interest on note payable	30,000	30	35,970	-	-	-	36,000
Issuance of warrants with notes payable in July and August 2004	_	_	72,252	_	_	_	72,252

	Common S Shares	tock Amount	Additional Paid-In Capital		mmon tock Accur scribed De		Total
Accrued deferred compensation in August 2004 to a consultant for 10,000 shares at \$1.00 per share, committed but unissued	_	_	_	(10,000)	_	_	(10,000)
Shares issued in August 2004 at \$1.40 to a consultant for services to be performed through October 2004	10,000	10	13,990	(14,000)	-	-	-
Shares issued in August 2004 at \$1.25 per share for conversion of \$30,000 demand loan	24,000	24	29,976	_	-	_	30,000
Shares issued in August 2004 at \$1.60 per share to a consultant for services provided.	12,500	13	19,988	_	-	_	20,000
Shares issued to employees in September, 2004 at \$1.60 to \$2.50 per share	4,880	5	8,379	_	-	_	8,384

Commitment to issue 10,000 shares of stock to a consultant in September, 2004 at \$2.30 per share for services to be provided through September 2005	_	-	<u>-</u>	(23,000)	_	<u>-</u>	(23,000)
Sale of stock for cash in October at \$1.25 per share, net of costs of \$298,155	1,816,000	1,816	1,362,107	-	-	-	1,363,923
Value of warrants issued with sale of common stock in October, net of costs	_	_	607,922	_	<u>-</u>	_	607,922
Issuance of warrant to officer in October, 2004	<u>-</u>	-	112,697	-	-	-	112,697
Issuance of stock to investment bankers in October 2004 for commissions earned	490,000	490	(490)	-	-	<u>-</u>	-
Conversion of accounts payable to stock in October, 2004 at \$1.25 per share	125,775	126	108,514	_	-	-	108,640
Value of warrants issued with accounts payable	-	-	48,579	-	-	-	48,579

conversions in October, 2004							
Conversion of demand loan to stock in October, 2004 at \$1.10 per share	9,330	9	10,254	_	-	-	10,263
Forgiveness of notes payable in October, 2004	-	-	36,785	-	-	-	36,785

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

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	Common Shares	Stock Amount	Additional Paid-In Capital	Deferred Compensation	Common Stock Subscribed	Accumulated Deficit	Total
Issuance of stock to officer and director at \$1.25 per share in October, 2004 for conversion of liability	144,000	144	123,789	_	_	_	123,933
Value of warrants issued with officer and director conversion of liabilities in October, 2004	-	-	56,067	-	-	-	56,067
Conversion of debt and accrued interest to common stock at \$0.75 to \$1.25 per share in October, 2004	670,315	670	423,547	-	-	-	424,217
Value of warrants issued with conversion of debt in October, 2004	-	-	191,111	-	-	-	191,111
Conversion of Note Payable of \$5,000 plus accrued interest of \$71 in	6.761	_	4.000				5.000
October, 2004	6,761	7	4,993	-	-	-	5,000
	-	-	112,562	-	-	-	112,562

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Issuance of warrants to note holders in October, 2004							
Value of shares issued to CFO as compensation in December, 2004	10,000	10	34,990	-	-	-	35,000
Value of warrants issued to members of advisory committees in November and December, 2004			16,348				16,348
December, 2004	-	-	10,546	-	-	-	10,546
Beneficial conversion feature associated with notes payable in December, 2004	_	_	124,709	_	_	_	124,709
Shares issued in error to be cancelled in December, 2004	(900 )	(1	) 1	_	_	_	0
Amortization of deferred compensation through December 31, 2004	-	-	-	2,729,454	-	-	2,729,454
Loss for the twelve months ended December 31, 2004	_	-	-	-	-	(5,305,407)	(5,305,407)
Balance at December 31, 2004	6,242,339	\$6,242	\$7,979,124	\$ (169,986	) \$-	\$ (7,208,027)	\$607,353

	Common Shares	Stock Amount	Additional Paid-In Capital	Deferred Compensation	Common Stock Subscribed	Accumulated Deficit	Total
Sale of shares of common stock for cash at \$2.00 per share in March 2005 for warrant exercise, net of costs	660,078	660	1,190,196	_	_	-	1,190,856
Value of warrants issued to members of advisory committees in March 2005	_	_	137,049	_	_	_	137,049
Deferred compensation in February 2005 to a consultant for 5,000 shares of common stock at \$6.50 per share.	-	-	_	(32,500)	_	-	(32,500)
Warrants exercised at \$0.50 per share in June 2003	8,000	8	3,992	-	-	-	4,000
Value of warrants issued to members of advisory committee in June 2005	_	-	70,781	-	<u>-</u>	_	70,781
Value of warrants issued to investors and	-	-	32,991	-	-	-	32,991

service providers in June 2005							
Issuance of 23,215 shares of common stock in July 2005 for conversion of notes payable	23,215	23	64,980	_	-	_	65,003
Issuance of 10,000 shares of common stock in August 2005 to a consultant for services provided	10,000	10	9,990	-	-	-	10,000
Value of warrants issued to advisory committee in September 2005 for services	-	_	20,491	-	-	-	20,491
Amortization of deferred comp for the twelve months ended December, 2005	-	-	-	199,726	-	-	199,726
Value of warrants issued in October and December 2005 to investors and service providers	-	-	18,399	-	-	-	18,399
Loss for the year ended December 31,2005	6,943,632	\$ 6,943	\$ 9,527,993	\$ (2,760) \$	- S - \$	(4,591,107) (11,799,134)	(4,591,107) \$ (2,266,958)
The accompan	ying notes a	re an integral	part of these u	naudited condense	ed consolidat	ed financial sta	atements.

	Common Shares	Stock Amount	Additional Paid-In Capital	Deferred Compensation	Common Stock Subscribed	Accumulated Deficit	Total
Issuance of 10,000 shares to officer, previously accrued in March, 2006	10,000	10	41,406	<u>-</u>	-	-	41,416
Value of warrants issued to members of advisory committee in March, 2006	-	-	8,399	<u>-</u>	-	-	8,399
Amortization of deferred compensation for the three months ended March 31, 2006	-	-	_	2,760	-	-	2,760
Issuance of common stock in May 2006 to a consultant for services provided	3,446	3	16,194	-	-	-	16,197
Conversion of accrued interest to common stock at \$1.25 per share in May, 2006	1,929	2	2,409	-	-	<u>-</u>	2,411
Conversion of accrued interest to common stock at \$1.25 per	1,632	2	2,039	-	-	-	2,041

share in May, 2006							
Conversion of accrued interest to common stock at \$1.00 per share in May, 2006	1,345	1	1,354	<u>-</u>	-	-	1,355
Common stock issued pursuant to the exercise of warrants at \$0.90 per share in June 2006	500	1	450	-	-	-	450
Value of warrants issued to members of advisory committee in June 2006	-	-	8,820	-	-	_	8,820
Value of warrants issued to members of advisory committee in September 2006	_	_	3,495	_	_	_	3,495
Value of warrants issued to officers in September, 2010	-	_	50,874	_	-	_	50,874
Issuance of penalty Common Stock, previously accrued in August, 2006	415,080	415	871,250	_	_	_	871,665
Issuance of penalty warrants, previously accrued in August, 2006	_	-	182,239	_	-	-	182,239
Value of options issued to officer in September,	-	-	78,802	-	-	-	78,802

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2006							
Value of warrants issued to members of advisory committee in December 2006			1,974			-	1,974
Issuance of Common Stock for cash in December, 2006	3,426,625	3,427	4,610,122	-	-	-	4,613,549
Common stock to be issued as commission for equity fund raising in December, 2006	_	_	(5,483)	_	5,483	_	_
Value of options issued to officer in October, 2006			185,472			-	185,472
Value of shares issued to officer in March, 2006	-	-	32,120	-	-	-	32,120
Loss for the year ended December 31, 2006	10,804,190	\$ 10,804	\$ 15,619,928	- \$ -	\$ 5,483	(1,486,046) \$(13,285,180)	(1,486,046) \$ 2,351,035

	Common Shares	Stock Amount	Additional Paid-In Capital	Deferred Compensation	Common Stock Subscribed	Accumulated Deficit	Total
Common stock issued as commission for equity fund raising in January, 2007	548,260	548	4,935	-	(5,483)	-	_
Common stock issued to consultant in January 2007 at \$1.50 per share	29,804	30	44,676	_	-	-	44,706
Common stock issued to consultants in January 2007 at \$1.55 per share	40,000	40	61,960	_	-	-	62,000
Common stock issued to consultants in January 2007 at \$1.50 per share	10,000	10	14,990	_	-	-	15,000
Value of options issued to officer in January, February and March 2007	-	-	471,457	_	-	-	471,457
Value of options issued to employee in January 2007	_	_	5,426	_	-	-	5,426
Value of warrants issued	-	-	166,998	-	-	-	166,998

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to consultant in April 2007							
Value of options issued to employees in July 2007			996,133	-	_		996,133
Value of options issued to directors in July 2007			537,833	_	_	-	537,833
Value of options issued to consultants in July 2007			80,996	_	_		80,996
Common stock to be issued for consulting services in 2008 at \$1.10 per share in November, 2007	_		_	_	33,000	-	33,000
Common stock to be issued for finders fee in 2008 at \$1.20 per share in November, 2007	-			_	120,000	-	120,000
Loss for the year ended December 31, 2007	11,432,254	\$ 11,432	2 \$18,005,332	- \$ -	- \$ 153,000	(5,463,958) \$ (18,749,138)	(5,463,958) \$ (579,374)

	Common Shares	Stock Amount	Additional Paid-In Capital	Deferred Compensation	Common Stock Subscribed	Accumulated Deficit	Total
Common stock issued for consulting services previously accrued in November 2007	30,000	30	32,970	-	(33,000)	-	_
Common stock issued for finders fee previously accrued in November 2007	100,000	100	119,900	_	(120,000)	_	_
Value of warrants issued pursuant to convertible debt agreement in January 2008	_	_	226,754	_	_	-	226,754
Adjustment to value of warrants issued in January 2008 due to decrease in exercise price	_	_	60,092	_	_	_	60,092
Value of options issued to advisory board in March 2008	-	-	3,729	_	-	-	3.729
Value of options issued to employee in January 2007	-	-	5,428 6,994	-	-	-	5,428 6,994

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Value of options issued to consultants in July 2007							
C 1 -							
Common stock issued for March 2008 interest							
payment at \$0.488 per share	39,500	39	19,237				19,276
per snare	39,300	39	19,237	-	-	-	19,270
Value of options issued to employees in			1 700				1 700
March 2008	-	-	1,708	-	-	-	1,708
Value of options issued to a Director in March			40.62				10.505
2008	-	-	19,625	-	-	-	19,625

	Common S Shares	Stock Amount	Additional Paid-In Capital	Deferred Compensation	Common Stock Subscribed	Accumulated Deficit	Total
Common stock issued for June 2008 interest payment at \$0.699 per share in July 2008	28,220	28	19,698	-	-	<u>-</u>	19,726
Common stock issued for June 2008 interest payment at \$0.699 per share in July 2008	2,822	3	1,969	_	-	-	1,972
Common stock issued for interest payment at \$0.33032 per share in August 2008	95,825	96	31,557	_	_	_	31,653
Common stock issued for interest payment at \$0.33032 per share in August 2008	2,228	2	734	-	-	<del>-</del>	736
Common stock issued for interest payment at \$0.33032 per share in August 2008	124,794	125	41,097	_	_	-	41,222
Common stock issued for pre-payment of	162,721	163	53,587	-	-	-	53,750

interest payment at \$0.33032 per share in August 2008							
Common stock issued for pre-payment of interest payment at \$0.33032 per share in August 2008	3,785	4	1,246	_	<u>-</u>	_	1,250
Common stock issued for pre-payment of interest payment at \$0.33032 per share in August 2008	211,916	212	69,788				70,000
2008	211,910	212	09,788	-	-	-	70,000
Common stock issued pursuant to the exercise of warrants at \$0.375 per share in June and July 2008	30,000	30	11,220	-	<u>-</u>	<u>-</u>	11,250
Common stock issued for rounding due to reverse stock split in August 2008	126	1	(1)	-	_	_	_
Common stock subscribed pursuant to agreement for capital raise in August 2008	_	_	-	-	250,000	-	250,000
Value of warrants issued pursuant to convertible debt agreement in							
August 2008	-	-	286,846	-	-	-	286,846
	-	-	427,628	-	-	-	427,628

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Value of warrants issued pursuant to convertible debt agreement in August 2008								
Value of warrants issued pursuant to convertible debt agreement in August 2008	-	_	9,946		-	-	-	9,946
Value of warrants issued pursuant to convertible debt agreement in August 2008	-	-	556,949		-	-	-	556,949
Value of options issued to directors in November 2008	_	-	52,284		-	_	-	52,284
Loss for the year ended December 31, 2008	-	-	-		-	-	(5,807,353)	(5,807,353)
Balance at December 31, 2008	12,264,191	\$ 12,265	\$ 20,066,317	\$	- \$	250,000	\$ (24,556,491)	\$ (4,227,909)

	Common Shares	Stock Amount	Paid-In Capital	Additional Deferred Compensation	Stock Subscribed	Common Accumulated Deficit	Total
Cumulative effect of change in accounting principle-January 1, 2009 reclassification of embedded feature of equity-linked financial instrument to derivative liability		_	(1,856,576)	·	_	3,259,335	1,402,759
Common stock issued pursuant to agreement for capital raise previously accrued in August 2008 at \$0.30 per share	833,334	833	249,167	_	(250,000)	_	_
Value of options issued to employees in March 2008	_	_	244	-	_	_	244
Loss for the three months ended March 31, 2009	-	-	-	-	-	(2,141,047)	(2,141,047)
Balance at March 31, 2009	13,097,525	\$ 13,098	\$ 18,459,152	\$ -	\$ -	\$ (23,438,203)	\$ (4,965,953)
Common stock to be issued for consulting services performed from	-	-	-	-	38,000	-	38,000

June to August 2009 at \$0.19 per share							
Loss for the three months ended June 30, 2009	-	-	-	-	-	(2,028,639)	(2,028,639)
Balance at June 30, 2009	13,097,525	\$ 13,098	\$ 18,459,152	\$ -	\$ 38,000	\$ (25,466,842)	\$ (6,956,952)
Common stock issued for consulting services performed from June to August 2009 at \$0.19 per share, previously accrued	200,000	200	37,800	_	(38,000)	_	_
Common stock to be issued for consulting services performed in September 2009 at \$0.36 per share	_	_	-	_	16,000	-	16,000
Value of options issued to advisory board in Aug 2009	-	-	4,045	-	-	-	4,045
Value of options issued to consultants in Aug 2009	-	-	1,458	-	-	-	1,458
Value of options issued to employees in Aug 2009	-	-	2,500	-	-	-	2,500
Value of options issued to Officers and Directors in Aug 2009	-	-	37,917	-	-	-	37,917
Loss for the three months ended	-	-	-	-	-	(3,024,156)	(3,024,156

September 30, 2009

Balance at September 30,

2009 13,297,525 \$ 13,298 \$18,542,872 \$ - \$ 16,000 \$(28,490,998) \$(9,918,828)

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

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Cash flows from financing activities:

IR BioSciences Holdings, Inc. and Subsidiary
(A Development Stage Company)
Condensed Consolidated Statements of Cash Flows
For the Nine Months Ended September 30, 2009 and 2008,
And For the Period of Inception (October 30, 2002) to September 30, 2009
(Unaudited)

	For the Nine Months Ended September 30, 2009	For the Nine Months Ended September 30,	Cumulative from Inception (October 30, 2002) to September 30, 2009
Cash flows from operating activities:			
Net loss	\$ (7.193.842)	\$ (4.129.657)	\$ (28,490,998)
Adjustments to reconcile net loss to net	, (,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	( ) - )	1 ( 2) 2 2) 2
cash used in operating activities:			
Non-cash compensation	100,164	313,383	7,248,291
Cost of penalty for late registration of shares - stock portion	-	-	1,631,726
Cost of penalty for late registration of shares - warrant portion	-	-	560,434
(Gain) loss from marking to market - stock portion of penalty for late			
registration of shares	-	-	(760,058)
(Gain) loss from marking to market - warrant portion of penalty for late			
registration of shares	-	-	(378,198)
Change in fair value of derivative liability	3,082,961	-	(489,734)
Legal fees for note payable	-	-	20,125
Placement fees for note payable	-	-	65,000
Impairment of intangible asset	-	-	6,393
Interest expense	600,000	-	1,174,880
Amortization of discount on notes payable	799,907	(11,234)	2,338,482
Redemption Option Liability	225,000	-	225,000
Depreciation and amortization	10,937	90,352	80,024
Changes in operating assets and liabilities:			
Increase in deposits	(315)	-	(5,183)
Decrease in prepaid services and other assets	139,856	38,430	210,328
Increase/(Decrease) in accounts payable and accrued expenses	(134,560)	(36,372)	974,120
Net cash used in operating activities	(2,369,892)	(3,735,098)	(15,589,368)
Cash flows from investing activities:	(4. =0.0)	(1 = 0.40)	(0.5.777)
Acquisition of property and equipment	(1,500)	(15,048)	(86,577)
	/ ·	/4 = 0 · = ·	(0.5.775
Net cash used in investing activities	(1,500)	(15,048)	(86,577)

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Proceeds from notes payable	-	7,818,889	9,668,375
Principal payments on notes payable and demand loans	-	-	(1,094,747)
Shares of stock sold for cash	-	-	7,873,451
Proceeds from exercise of warrant	-	11,250	15,700
Officer repayment of amounts paid on his behalf	-	-	19,880
Cash paid on behalf of officer	-	-	(19,880)
Net cash provided by financing activities	-	7,830,139	16,462,779
Net (decrease) increase in cash and cash equivalents	(2,371,392)	4,079,993	786,834
Cash and cash equivalents at beginning of period	3,158,226	221,120	-
Cash and cash equivalents at end of period	\$ 786,834	\$ 4,301,113	\$ 786,834

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

## **Table of Contents**

IR BioSciences Holdings, Inc. and Subsidiary
(A Development Stage Company)
Condensed Consolidated Statements of Cash Flows
For the Nine Months Ended September 30, 2009 and 2008,
And For the Period of Inception (October 30, 2002) to September 30, 2009
(Unaudited)
(continued)

Supplemental disclosures of cash flow information:		For the Ni Ended Sep 2009			S	For the Period october 30, 2002 to September 30, 2009
Cook maid dyning the namind form						
Cash paid during the period for: Interest	\$	_	\$	40,998	\$	127,051
interest	Ψ	_	Ψ	40,770	Ψ	127,031
Taxes	\$	-	\$	-	\$	8,115
Acquisition and capital restructure:						
Assets acquired		-		-		-
Liabilities assumed		-		-		(120,799)
Common stock retained		-		-		(2,369)
Adjustment to additional paid-in capital		-		-		123,168
Organization costs		-		-		350,000
Total consideration paid	\$	-	\$	-	\$	350,000
Common stock issued in exchange for proprietary rights	\$	-	\$	-	\$	9,250
Common stock issued in exchange for services	\$	38,000	\$	-	\$	3,215,483
Common stock to be issued in exchange for services rendered	\$	16,000	\$	-	\$	16,000
Common stock issued in exchange for previously incurred debt and accrued interest	\$		\$	-	\$	1,066,401
Common stock issued in exchange as interest	\$	-	\$	114,585	\$	150,585
Amortization of beneficial conversion feature	\$	-	\$	-	\$	223,269
Stock options and warrants issued in exchange for services rendered	\$	46,164	\$	63,383	\$	3,790,841
Debt and accrued interest forgiveness from note holders	\$	-	\$	-	\$	36,785
Common stock issued in satisfaction of amounts due to an Officer and a Director	\$	-	\$	-	\$	180,000

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Common stock issued in satisfaction of accounts payable	\$ -	\$ -	\$ 157,219
Deferred compensation to a consultant accrued in March 2005	\$ -	\$ -	\$ 2,630,761
Amortization of deferred compensation	\$ -	\$ -	\$ 202,486
Fair value of common stock and warrants in payable in connection with late filing of registration statement	\$ -	\$ -	\$ 3,684,664
Gain from marking to market - stock portion of penalty for late registration of shares	\$ -	\$ -	\$ (1,124,255)
Gain from marking to market - warrant portion of penalty for late registration of shares	\$ -	\$ -	\$ (456,603)
Revaluation of derivative liability	\$ 3,082,961	-	\$ (489,734)
Impairment of intangible asset	\$ -	\$ -	\$ 6,393
Issuance of stock to Officer, previously accrued	\$ 250,000	\$ -	\$ 291,416
Services for note payable	\$ -	\$ -	\$ 9,750
Issuance of shares for accounts payable	\$ -	\$ 44,706	\$ 44,706
Stock issued as commission for equity fund raising	\$	\$ 120,000	\$ 125,483
Value of warrants issued for financing	\$ -	\$ 1,568,215	\$ 1,568,215

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

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# IR BIOSCIENCES HOLDINGS, INC. AND SUBSIDARY (A DEVELOPMENT STAGE COMPANY) NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS SEPTEMBER 30, 2009 (Unaudited)

Note 1 - Summary Of Accounting Policies

#### General

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with the instructions to Form 10-Q, 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- and nine-month periods ended September 30, 2009 are not necessarily indicative of the results that may be expected for the year ended December 31, 2009. The unaudited condensed consolidated financial statements should be read in conjunction with the December 31, 2008 financial statements and footnotes thereto included in the Company's annual report on SEC Form 10-K filed with the Securities and Exchange Commission on March 31, 2009 and as amended on April 30, 2009.

#### Business and basis of presentation

IR BioSciences Holdings, Inc. (the "Company," "we," or "us") formerly GPN Network, Inc. ("GPN") is currently a development stage company as set forth in Accounting Standard Codification (ASC). The Company, which was incorporated under the laws of the State of Delaware on October 30, 2002, is a development-stage biopharmaceutical company. Through our wholly-owned subsidiary, ImmuneRegen BioSciences, Inc., the Company is engaged in the research and development of potential drugs. The Company's goal is to develop therapeutics to be used for the protection of the body from exposure to harmful agents such as toxic chemicals and radiation, as well as, biological agents, including influenza and anthrax. The Company's research and development efforts are at a very early stage and Radilex and Viprovex, the Company's potential drug candidates, 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 unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, ImmuneRegen BioSciences, Inc. Significant inter-company transactions have been eliminated in consolidation.

In July 2003, the Company effected a 1-for-20 reverse stock split of its common stock. In April 2004, the Company effected a 2-for-1 forward split of its common stock. On July 10, 2008, the Company effected a 1-for-10 reverse stock split of its common stock and simultaneously reduced its total authorized shares of common stock to 100,000,000. Par value remained unchanged as a result of the July 2008 stock split and reduction of authorized shares. Accordingly, the effect of the reverse-split has been presented in the accompanying unaudited condensed consolidated financial statement and footnote disclosures.

## Reclassification

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

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#### Stock based compensation

In accordance with GAAP regarding "Share-Based Payment," (which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors including employee stock options based on estimated fair values), we are using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006.

Under the modified prospective approach, Share-Based Payment applies to new awards and to awards that were outstanding on January 1, 2006 that are subsequently modified, repurchased or cancelled. Under the modified prospective approach, compensation cost recognized in the nine months of fiscal 2006 includes compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of Share-Based Payments, and compensation cost for all share-based payments granted subsequent to January 1, 2006 based on the grant-date fair value estimated in accordance with the provisions of Share Based Payments. Prior periods were not restated to reflect the impact of adopting the new standard.

A summary of option activity under the Company's stock option plan as of September 30, 2009, and changes during the period ended are presented below:

	Options	Ay Ex	eighted verage kercise Price
Outstanding at December			
31, 2008	1,791,168	\$	2.65
Issued	1,021,235	\$	0.25
Exercised	-		-
Forfeited or expired	-		-
Outstanding at			
September 30, 2009	2,812,403	\$	1.78
Non-vested at September			
30, 2009	753,750	\$	0.25
Exercisable at September			
30, 2009	2,058,653	\$	2.34

Aggregate intrinsic value of options outstanding and exercisable at September 30, 2009 was \$0. Aggregate intrinsic value represents the difference between the Company's closing stock price on the last trading day of the fiscal period, which was \$0.35 as of September 30, 2009, and the exercise price multiplied by the number of options outstanding. As of September 30, 2009, total unrecognized stock-based compensation expense related to stock options was \$209,375. The total fair value of options vested during the three months ended September 30, 2009 was \$45,920.

#### Interim financial statements

The accompanying balance sheet as of September 30, 2009, the statements of operations for the three- and nine-months ended September 30, 2009 and 2008, and for the period of inception (October 30, 2002) to September 30, 2009, and the statements of cash flows for the nine months ended September 30, 2009 and 2008, and from the period of inception (October 30, 2002) to September 30, 2009 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.

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#### 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

Intangible and long-lived assets to be held and used 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

Prepaid services and other current assets at September 30, 2009 and December 31, 2008 consist of the following:

	ptember 0, 2009	ecember 1, 2008
Prepaid monitoring fees	\$	\$ 140,625
Prepaid insurance	11,001	44,929
Prepaid services	14,286	22,834
Prepaid car lease	-	11,865
Prepaid software	10,000	-
Salary advance	-	1,765
Total prepaid services		
and other current assets	\$ 82,162	\$ 222.018

## Deposits and other assets

The balance consists of a deposit on leased office space in the amount of \$7,693 and \$7,378 as of September 30, 2009 and December 31, 2008, respectively.

#### Advertising

The Company follows the policy of charging the costs of advertising to expenses incurred. The Company did not incur any advertising costs during the three months ended September 30, 2009 or during the year ended December 31, 2008.

## Derivative Instruments and Hedging

In June 2008, the FASB issued new accounting guidance which requires entities to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock by assessing the instrument's contingent exercise provisions and settlement provisions. See Note 5.

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#### **Recent Accounting Pronouncements**

Accounting Standards Codification and GAAP Hierarchy — Effective for interim and annual periods ending after September 15, 2009, the Accounting Standards Codification and related disclosure requirements issued by the FASB became the single official source of authoritative, nongovernmental GAAP. The ASC simplifies GAAP, without change, by consolidating the numerous, predecessor accounting standards and requirements into logically organized topics. All other literature not included in the ASC is non-authoritative. We adopted the ASC as of September 30, 2009, which did not have any impact on our results of operations, financial condition or cash flows as it does not represent new accounting literature or requirements. All references to pre-codified U.S. GAAP have been removed from this Form 10-Q.

Subsequent Events — Effective for interim and annual periods ending after June 15, 2009, GAAP established general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The new requirements do not change the accounting for subsequent events; however, they do require disclosure, on a prospective basis, of the date an entity has evaluated subsequent events. We adopted these new requirements as of September 30, 2009, which had no impact on our results of operations, financial condition or cash flows.

Transfers and Servicing – Effective for interim and annual periods beginning after November 15, 2009, GAAP eliminates the concept of a qualifying special purpose entity, changes the requirements for derecognizing financial assets and requires additional disclosures. We are currently assessing the future impact these new standards will have on our results of operations, financial position or cash flows.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the AICPA, and the SEC did not, or are not believed by management to, have a material impact on the Company's present or future consolidated financial statements.

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## Note 2 – Furniture and equipment

## Furniture and Equipment

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

Computer equipment	3 years
Laboratory equipment	3 years
Website	5 years
Furniture	7 years

Depreciation and amortization expense for the nine months ended September 30, 2009 and 2008 was \$10,937 and \$7,986, respectively. The amount depreciated from the date of inception (October 30, 2002) through September 30, 2009 was \$80,024. Company's furniture and equipment consists of the following:

	September 30, 2009		cember 1, 2008
Office Equipment	\$ 49,909	\$	49,909
Office Fixtures and			
Furniture	30,568		30,568
Website	28,600		27,100
Licensed Proprietary			
Rights	9,250		9,250
	118,327		116,827
Accumulated			
Depreciation and			
Amortization	(86,417)		(75,480)
	\$ 31,910	\$	41,347

Note 3 - Accounts Payable And Accrued Liabilities

Accounts payable and accrued liabilities at September 30, 2009 and December 31, 2008 are as follows:

	Se	September		ecember
		30,		31,
		2009		2008
Accounts payable and				
accrued liabilities	\$	669,316	\$	776,319
Accounts payable -				
Pre-merger		34,926		34,926
Interest payable		3,215		3,215
Accrued payroll		-		-
Credit cards		17,709		45,266
State income tax payable		3,200		3,200
	\$	728,366	\$	862,926
	<b>\$</b>	728,366	<b>\$</b>	862,926

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Note 4 - Notes Payable

Note Issued To YA Global Investments, L.P. For Accrued Interest

On September 30, 2009, per the terms of the amended Securities Purchase Agreement with YA Global, the Company issued two 0% interest convertible debentures with a five year term of exercise and a conversion price of \$0.34 per share, subject to adjustment, as payment of an aggregate of \$75,000 in interest accrued during the three months ended September 30, 2009.

Note Issued To Funds Managed by Brencourt Advisors, LLC For Accrued Interest

On September 30, 2009, per the terms of the amended Securities Purchase Agreement with Funds Managed by Brencourt Advisors, LLC the Company issued four 0% interest convertible debentures with a five year term of exercise and a conversion price of \$0.34 per share, subject to adjustment, as payment of an aggregate of \$125,000 in interest accrued during the three months ended September 30, 2009.

As of September 30, 2009 and December 31, 2008 notes payable consist of:

	September 30, 2009	December 31,2008
YA Global Investments,		
L.P. Debentures	\$ 3,000,000	\$ 3,000,000
Note Issued To YA		
Global Investments, L.P.		
For Accrued Interest	368,889	143,889
Brencourt Advisors, LLC		
Debentures	5,000,000	5,000,000
Note Issued To		
Brencourt Advisors, LLC		
For Accrued Interest	500,000	125,000
Less: Debt discount	(3,165,709)	(1,474,937)
Total note payable	5,703,180	6,793,952
Less: current portion of		
notes payable	1,500,000	1,500,000
Total long term portion		
of notes payable	4,203,180	5,293,952

Aggregate maturities of long-term debt as of September 30, 2009 are as follows:

For the twelve months ended	
December 31,	Amount
2009	\$ 1,500,000
2010	1,500,000
2011	-
2012	-
2013 and beyond	5,868,889
	\$ 8,868,889

Note 5 – Derivative Liability

In accordance with Accounting for Derivative Instruments and Hedging mandates a two-step process for evaluating whether an equity-linked financial instrument or embedded feature is indexed to the entity's own stock. The Company has entered into certain debenture and warrant agreements which contain a strike price adjustment feature resulted in the instruments no longer being considered indexed to the Company's own stock. Accordingly, Accounting for Derivative Instruments and Hedging changed the current classification (from equity to liability) and the related accounting for these warrants outstanding as of January 1, 2009. During the first quarter of 2009, the liability was adjusted for warrants exercised and the change in fair value of the warrants. In accordance with Accounting for Derivative Instruments and Hedging, a derivative liability of \$4,170,881 related to the debenture conversion feature and warrants is included in our unaudited condensed consolidated balance sheet as of September 30, 2009. During the three- and nine- months ended September 30, 2009, we recorded a loss of \$1,706,401 and \$3,082,961 related to the change in fair value of the debenture conversion feature and warrants.

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In accordance to the Accounting for Derivative Instruments and Hedging, the Company is required to disclose the fair value measurements required by Accounting for Fair Value Measurements. The other liabilities recorded at fair value in the balance sheet as of September 30, 2009 are categorized based upon the level of judgment associated with the inputs used to measure their fair value. Hierarchical levels, defined by Fair Value Measurements are directly related to the amount of subjectivity associated with the inputs to fair valuation of these liabilities are as follows:

- Level 1 Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;
- Level 2 Inputs other than Level 1 inputs that are either directly or indirectly observable; and
- Level 3 Unobservable inputs, for which little or no market data exist, therefore requiring an entity to develop its own assumptions.

The following table summarizes the financial liabilities measured at fair value on a recurring basis as of September 30, 2009, segregated by the level of the valuation inputs within the fair value hierarchy utilized to measure fair value:

					Liabilities
	Leve	l 1	Level 2	Level 3	at fair value
Notes payable	\$	-	\$ -	\$ 5,703,180	\$ 5,703,180
Derivative liability		-	-	4,170,881	4,170,881
Total	\$	-	\$ -	\$ 9,874,061	\$ 9,874,061

In accordance with Accounting for Derivative Instruments and Hedging, we calculated the fair value of the debenture conversion features and warrants using the Black–Scholes–Merton valuation model.

The assumptions used in the Black-Scholes-Merton valuation model were as follows:

	January 1,	September 30,
	2009	2009
Expected volatility	189.77 %	349.02 %
Expected life (years)	4.40-5.51	2.97-5.00
Risk free interest rate	1.13 %	1.48 %
Forfeiture rate	-	-
Dividend rate	-	-

Note 6 - Equity

#### Common stock

In July 2003, the Company effected a 1-for-20 reverse stock split of its common stock. In April 2004, the Company effected a 2-for-1 forward split of its common stock. On July 10, 2008, the Company effected a 1-for-10 reverse stock split of its common stock and simultaneously reduced its authorized shares of common stock to 100,000,000; par value remained unchanged. Accordingly, the effect of the reverse-split has been presented in the accompanying unaudited condensed consolidated financial statement and footnote disclosures.

Issuance of Common Shares to Consultant

On June 1, 2009, the Company agreed to issue 200,000 shares of common stock to a consultant, 66,666 shares per month beginning June 30, 2009 for services to be rendered June 1, 2009 through August 31, 2009. Per the terms of the agreement, the contract may be extended on a month-to-month basis by mutual agreement for 44,444 shares per month. In August 2009, 133,332 shares were issued for services rendered and an additional 66,668, which includes two shares issued for rounding, shares were issued in September 2009. The securities were issued from the Company's 2003 Stock Option, Deferred Stock, Restricted Stock and Bonus Stock Plan. The value of the shares in the amount of \$38,000 has been recorded as common stock subscribed at June 30, 2009. During the three months ended September 30, 2009, the Company issued the 200,000 shares of common stock.

In October 2009, the parties agreed to extend the term of the agreement by two months; therefore, the Company is to issue an additional 44,444 shares of common stock to the consultant for services rendered September 1, 2009 to September 30, 2009. The securities are to be issued from the Company's 2003 Stock Option, Deferred Stock, Restricted Stock and Bonus Stock Plan. These shares were not issued as of September 30, 2009 and the fair value of these shares of \$16,000 has been recorded as common stock subscribed at September 30, 2009.

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#### **Options**

In August 2009, the Company issued options to purchase an aggregate of 910,000 shares of common stock to its officers and directors. Options vest in twelve month in equal quarterly installments, 25% each quarter beginning September 30, 2009. The Company valued these options at \$37,917. This amount will be charged to operations as the options vest.

In August 2009, the Company issued options to purchase an aggregate of 60,000 shares of common stock to its employees. Options vest in twelve month in equal quarterly installments, 25% each quarter beginning September 30, 2009. The Company valued these options at \$2,500. This amount will be charged to operations as the options vest.

In August 2009, the Company issued options to purchase an aggregate of 35,000 shares of common stock to three consultants. Options vest in twelve month in equal quarterly installments, 25% each quarter beginning September 30, 2009. The Company valued these options at \$1,458. This amount will be charged to operations as the options vest.

In August 2009, the Company issued options to purchase an aggregate 16,235 shares of common stock to members of its advisory boards for services performed in 2008. Options vest 30-days after issue. The Company valued these options at \$4,045 and was charged to operations at September 30, 2009.

The following table summarizes the changes in options outstanding and the related prices for the shares of the company's common stock issued to employees of the company under a non-qualified employee stock option plan September 30, 2009. The effect of the 1-for-10 reverse-split has been presented in the accompanying tables and related disclosures.

Options Outstanding			Options Exercisable			
		Weighted			Weighted	
		Average	Weighted		Average	
		Remaining	Average		Remaining	
Exercise	Number	Contractual	Exercise	Number	Contractual	
Prices	Outstanding	Life (years)	Price	Exercisable	Life (years)	
\$ 0.10-2.20	2,579,235	7.68	\$ 0.10-2.20	1,825,485	6.77	
2.30-2.50	201,444	1.77	2.30-2.50	201,444	1.77	
3.10	100	1.20	3.10	100	1.20	
3.30	10,303	0.89	3.30	10,303	0.89	
4.40	15,000	0.75	4.40	15,000	0.75	
250.00	6,321	0.50	250.00	6,321	0.50	
	2,812,403	7.18		2,058,653	6.19	

Options not vested are not exercisable. Transactions involving stock options issued to employees are summarized as follows:

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		W	eighted
		A	verage
	Number of	Pr	rice Per
	Shares	1	Share
Outstanding at December 31, 2008	1,791,168	\$	2.65
Granted	-		-
Exercised	-		-
Expired	-		-
Outstanding at March 31, 2009	1,791,168	\$	2.65
Granted	-		-
Exercised	-		-
Expired	-		-
Outstanding at June 30, 2009	1,791,168	\$	2.65
Granted	1,021,235		0.25
Exercised	-		-
Expired	-		-
Outstanding at September 30, 2009	2,812,403	\$	2.65
Non-vested at September 30, 2009	753,750	\$	0.25
Exercisable September 30, 2009	2,058,653	\$	2.34

Aggregate intrinsic value of options outstanding and exercisable at September 30, 2009 was \$0. Aggregate intrinsic value represents the difference between the Company's closing stock price on the last trading day of the fiscal period, which was \$0.35 as of September 30, 2009, and the exercise price multiplied by the number of options outstanding. As of September 30, 2009, total unrecognized stock-based compensation expense related to stock options was \$209,375. The total fair value of options vested during the three months ended September 30, 2009 was \$45,920.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model. We use historical data to estimate expected volatility, the period of time that option grants are expected to be outstanding, as well as employee termination experience. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the estimated life of the option. The following assumptions were used to estimate the fair value of options granted during the three-month periods ended September 30, 2009 and 2008 using the Black-Scholes option-pricing model:

	2009		2008	
Risk-free interest rate at				
grant date	1.48	%	4.25	%
			82.54%	
Expected stock price			to	
volatility	349.0	2%	93.11%	
Expected dividend				
payout	-		-	
Expected option				
life-years	3 to 10		3 to 5	

## Warrants

The Company issued no warrants during the three months ended September 30, 2009.

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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	
		Weighted			Weighted
		Average	Weighted		Average
		Remaining	Average		Remaining
Exercise	Number	Contractual	Exercise	Number	Contractual
Prices	Outstanding	Life (years)	Price	Exercisable	Life (years)
\$ 0.50-1.00	-	-	\$ 0.50-1.00	-	-
1.25-2.20	4,103,475	3.91	1.25-2.20	4,103,475	3.91
2.30-5.60	2,543,077	1.58	2.30-5.60	2,543,077	1.58
10.00	2,750	0.25	10.00	2,750	0.25
20.00	-	-	20.00	-	-
	6,649,302	3.01		6,649,302	3.01

Transactions involving warrants are summarized as follows:

		Weighted
		Average
	Number of	Price Per
	Shares	Share
	(post-split)	(post-split)
Outstanding at December 31, 2008	7,020,975	\$ 2.66
Granted	-	-
Exercised	-	-
Cancelled or expired	(102,548)	2.26
Outstanding at March 31, 2009	6,918,427	\$ 2.67
Granted	-	-
Exercised	-	-
Cancelled or expired	(62,350)	2.88
Outstanding at June 30, 2009	6,856,077	\$ 2.67
Granted	-	-
Exercised	-	-
Cancelled or expired	(206,775)	4.60
Outstanding at September 30, 2009	6,649,302	2.61

Note 7 - Subsequent Events

In accordance with FASB ASC 855"Subsequent Events", the Company has evaluated subsequent events through the date of the filing (November 16, 2009)

## Issuance of Common Shares to Consultant

On June 1, 2009, the Company agreed to issue 200,000 shares of common stock to a consultant, 66,666 shares per month beginning June 30, 2009 for services to be rendered June 1, 2009 through August 31, 2009. Per the terms of the agreement, the contract may be extended on a month-to-month basis by mutual agreement for 44,444 shares per

month. In October 2009, the parties agreed to extend the term of the agreement by two months; therefore, the Company is to issue an additional 44,444 shares of common stock to the consultant for services rendered September 1, 2009 to September 30, 2009 and 44,444 shares of common stock to the consultant for services rendered October 1, 2009 to October 31, 2009. The securities are to be issued from the Company's 2003 Stock Option, Deferred Stock, Restricted Stock and Bonus Stock Plan. The 44,444 shares for services rendered September 1, 2009 through September 30, 2009 were not issued as of September 30, 2009 and the fair value of these shares of \$16,000 has been recorded as common stock subscribed at September 30, 2009.

On October 16, 2009, the Company agreed to issue 50,000 shares of restricted common stock to a consultant for services to be rendered from October 16, 2009 to January 15, 2010.

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

Special Note Regarding Forward-looking Statements

Some of the statements under "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q constitute forward-looking statements. All statements other than historical facts contained in this report, including statements regarding our future financial position and revenues, capital expenditures, cash flows, business strategy and plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among other things, those described under "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q and in the "Risk Factors" section of our annual report on SEC Form 10-K filed with the Securities and Exchange Commission on March 31, 2009 and as amended on April 30, 2009.

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, we 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

IR BioSciences Holdings, Inc. is a development-stage biotechnology company. Through our wholly-owned subsidiary ImmuneRegen BioSciences, Inc., we are engaged in the research and development of potential drug candidates, Homspera® and its derivatives, Radilex® and Viprovex®. Although containing the identical active ingredient Homspera, we defined Radilex and Viprovex as derivatives of Homspera due to the potential difference in formulations and indications for use. Our goals include developing these potential drug candidates to be used as possible countermeasures for homeland security threats, including radiological, chemical and biological agents, and to meet the commercial need for similar beneficial effects in conditions such as radiation therapy, influenza, anthrax and potentially other microbial ailments. We have discovered activities of Homspera that may potentially open additional commercialization opportunities in areas such as human adult stem cell stimulation, vaccine adjuvants, which stimulate the immune system above that of a stand-alone vaccine, and wound healing.

Our patents, patent applications and continued research are partially derived from discoveries made during research studies related to the function of Substance P, which is found in the body and has a large number of actions. These studies were funded by the Air Force Office of Scientific Research (AFOSR) in the early 1990s and were conducted by research scientists, including our co-founders Drs. Mark Witten and David Harris. In the course of research on Substance P, scientists created a number of synthetic analogues, structural derivatives with slight chemical differences, for study. One of these, which we have named Homspera, is the basis for our drug development efforts and our intellectual property. All of our research and development efforts are at the pre-clinical stage and Homspera has only undergone exploratory studies to evaluate its biological activity in small animals. There can be no assurance

that our interpretation of study results will prove to be accurate after further testing, and our beliefs regarding the potential uses of our drug candidates may never materialize.

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Our current focus is to develop Homspera for regenerating or strengthening the human immune system, in part, through stimulating human adult stem cells. It is the belief of our management that the stem cell activity exhibited by Homspera underlies some of the effects previously reported in potential applications like treatment for radiation exposure and infectious diseases using Homspera derivatives Radilex and Viprovex, respectively, which are described below. Recent studies have evaluated the effects of Homspera on human adult stem cell activity. Additionally, ongoing studies are being performed to evaluate the efficacy of Homspera as a potential product to increase the healing rate of wounds. One aspect of this evaluation is to consider the impact of Homspera on the mechanisms and pathology of fibrosis, which is associated with scar formation, pulmonary injury and can occur following exposure to ionizing radiation (gamma rays or x-rays).

We are researching Radilex for use as a potential treatment for acute exposure to radiation. We believe that a commercial market may exist for the use of Radilex as it relates to the amelioration of certain side effects of cancer treatments, whether chemotherapy or radiotherapy.

We are researching Viprovex for potential use in treatments of exposure to biological agents, such as infectious diseases, which include influenza and anthrax. We believe that potential commercial opportunities may exist for the treatment of seasonal influenza and other viral or bacterial infections, either as a stand-alone drug or as an adjuvant to other existing drugs. We believe that Viprovex, if adequately developed, may be used in potential applications for sale to governments for the treatment of exposure to anthrax and pandemic influenza. In addition, ongoing studies are being performed to evaluate the efficacy of Viprovex as a vaccine adjuvant to enhance immune response to a given dose of vaccine for either prophylactic protection, such as influenza, or therapy, such as cancer.

To date we have submitted an Investigational New Drug application (IND) for Homspera to the U.S. Food and Drug Administration (FDA) for the treatment of Idiopathic Pulmonary Fibrosis. We have also submitted preliminary study data to the FDA and have been issued two Pre-Investigational New Drug (PIND) numbers, one for the potential use of Radilex in the treatment of acute radiation syndrome (PIND 63,255) and the other for the potential use of Viprovex in the treatment of avian influenza (PIND 73,709). We have evaluated and/or contracted with a number of FDA regulatory consultants to assist us in our preparation and submission of an IND application, a necessary prerequisite to human clinical studies, which can only follow after the FDA's allowance of our IND.

We have filed patent applications directed to various methods of using and compositions comprising Substance P analogues. As of September 30, 2009, we owned approximately 15 issued patents, including two issued U.S. patents and thirteen issued foreign patents. Also as of September 30, 2009 we had approximately 52 pending patent applications, including approximately 16 pending U.S. patent applications and approximately 36 pending foreign patent applications. All inventions embodied in these applications and issued patents have been assigned to the company by the inventors. In addition, we have entered into a license agreement with the University of Pittsburgh whereby we have licensed the University's ownership interest to a patent that was jointly filed with the University of Pittsburgh.

Our potential drug candidates, Homspera, Radilex and Viprovex, are at pre-clinical stages of development and may not be shown to be safe or effective in humans and may never receive regulatory approval. Neither Homspera, Radilex nor Viprovex have been tested in humans. There is no guarantee that regulatory authorities will ever permit human testing of Homspera, Radilex, Viprovex or any other potential products derived from Homspera. Even if such testing is permitted, neither Homspera, Radilex, Viprovex or any other potential drug candidates, if any, derived from Homspera may be successfully developed or shown to be safe or effective in humans.

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The results of our pre-clinical studies and clinical trials may not be indicative of future clinical trial results. A commitment of substantial resources to conduct time-consuming research, pre-clinical studies and clinical trials will be required if we are to develop any commercial applications using Homspera or any derivatives thereof. It is possible that partnerships and/or licensing agreements will not develop during the preclinical and/or clinical stages of development, if at all. Delays in planned patient enrollment in our future clinical trials may result in increased costs, program delays or both. None of our potential technologies may prove to be safe or effective in clinical trials. Approval of the FDA, or other regulatory approvals, including export license permissions, may not be obtained and even if successfully developed and approved, our potential applications may not achieve market acceptance. Any potential applications resulting from our programs may not be successfully developed or commercially available for a number of years, if at all.

To date, we have not obtained regulatory approval for, or commercialized any applications, using Homspera or any of its derivatives. We have incurred significant losses since our inception and we expect to incur annual losses for at least the next three years as we continue with our drug research and development efforts.

Results of Operations for the Three Month Periods Ended September 30, 2009 and September 30, 2008

#### Revenue

We have not generated any revenues from operations from our inception.

## Costs and Expenses

From our inception through September 30, 2009, we have incurred losses of \$28,490,998. These expenses were associated principally with equity-based compensation to employees and consultants, product development costs and professional services and interest expense.

For the three months ending September 30, 2009, Sales, General and Administrative expenses ("SG&A") were \$743,383, a decrease of \$1,033,325, or approximately 58%, compared to SG&A expenses of \$1,776,708 during the three months ended September 30, 2008. The decrease is mostly due to lower costs for legal and accounting expenses, lower payroll and related expenses, lower research and development expenses and lower non-cash compensation. For the three months ended September 30, 2009, this amount consisted primarily of research and development costs of \$134,164, payroll and related expenses of \$216,829, legal and accounting fees of \$135,034, consulting and professional fees of \$89,795 and non-cash compensation of \$61,920.

The Company expects SG&A to remain flat during the coming twelve months.

## Financing Cost

Financing costs were \$31,250 for the three months ended September 30, 2009, with no increase compared to financing costs of \$31,250 during the three months ended September 30, 2008. The Company deposited cash in the amount of \$250,000 held in escrow pursuant to the Securities Purchase Agreements with YA Global Investments, L.P. that were entered into in January 2008 and June 2008, of which \$175,000 was placed into escrow on January 3, 2008 and an additional \$75,000 was placed into escrow on June 12, 2008. These funds are amortized on a straight-line basis over a 24 month period. Prior to December 31, 2008, these costs were captured in SG&A expenses.

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The Company expects no significant increase to financing costs during the coming twelve months.

Interest Expense (net)

Interest expense (net) was \$543,122 for the three months ended September 30, 2009, an increase of \$337,317 or approximately 164% compared to interest expense of \$205,805 for the three months ended September 30, 2008. Interest expense increased during the three months ended September 30, 2009 due to interest costs relating to a subsequent securities purchase agreement with YA Global Investments in June 2008 and a securities purchase agreement with a group of funds represented by Brencourt Advisors in August 2008.

The Company expects interest expense to remain flat during the coming quarters.

#### Net Loss

Our net loss for the three months ended September 30, 2009 was \$3,024,156 or \$0.23 per share, an increase of \$1,010,393 or approximately 50% compared to a net loss of \$2,013,763 for the three months ended September 30, 2008. In addition to the year over year variances described above, the increase in net loss was primarily due to a loss in the three month period ending September 30, 2009 of \$1,706,401 which was due to the change in value of the equity-linked financial instruments as mandated by ASC Accounting for Derivative Instruments and Hedging. (See Note 5 of the Notes to condensed consolidated financial statements, September 30, 2009 – Derivative Liabilities).

Results of Operations for the Nine Month Periods Ended September 30, 2009 and September 30, 2008

#### Revenue

We have not generated any revenues from operations from our inception.

#### Costs and Expenses

For the nine months ending September 30, 2009, Sales, General and Administrative expenses ("SG&A") were \$2,408,251, a decrease of \$1,263,001, or approximately 34%, compared to SG&A expenses of \$3,671,252 during the nine months ended September 30, 2008, mostly due to lower costs for: research and development; consulting and professional fees; legal and accounting; non-cash compensation; and, and payroll and related expenses. For the nine months ended September 30, 2009, this amount consisted primarily of research and development costs of \$482,584, payroll and related expenses of \$741,300, legal and accounting fees of \$534,121, consulting and professional fees of \$217,011, insurance costs of \$112,472, travel and entertainment expenses of \$82,806, public relations and marketing expenses of \$25,398 and facilities expenses of \$70,721.

## Financing Cost

Financing costs were \$93,750 for the nine months ended September 30, 2009, a 37% decrease compared to financing costs of \$148,125 during the nine months ended September 30, 2008. The decrease is primarily due to legal and associated closing costs for the Securities Purchase Agreements with YA Global incurred in the first nine months of 2008. Further, the Company deposited cash in the amount of \$250,000 held in escrow pursuant to the Securities Purchase Agreements with YA Global Investments, L.P. that were entered into in January 2008 and June 2008, of which \$175,000 was placed into escrow on January 3, 2008 and an additional \$75,000 was placed into escrow on June 12, 2008. These funds are amortized on a straight-line basis over a 24 month period. Prior to December 31, 2008, these costs were captured in SG&A expenses.

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The Company expects no significant increase to financing costs from current levels, during the coming twelve months.

## Interest Expense (net)

Interest expense (net) was \$1,608,880 for the nine months ended September 30, 2009, an increase of \$1,298,600 or approximately 418% compared to interest expense of \$310,280 for the nine months ended September 30, 2008. Interest expense increased during the nine months ended September 30, 2009 due to interest costs relating to the securities purchase agreement with YA Global Investments, L.P. in first quarter of 2008 and a subsequent securities purchase agreement with YA Global Investments in June 2008 and a securities purchase agreement with a group of funds represented by Brencourt Advisors in August 2008.

The Company expects interest expense to remain flat during the coming quarters.

#### Net Loss

Our net loss for the nine months ended September 30, 2009 was \$7,193,842 or \$0.55 per share, an increase of \$3,064,185 or approximately 74% compared to a net loss of \$4,129,657 for the nine months ended September 30, 2008. In addition to the year over year variances described above, the increase in net loss was primarily due to a loss in the nine month period ending September 30, 2009 of \$3,082,961 which was due to the change in value of the equity-linked financial instruments as mandated by ASC Accounting for Derivative Instruments and Hedging. (See Note 5 of the Notes to condensed consolidated financial statements, September 30, 2009 – Derivative Liabilities).

## Going Concern

Our independent certified public accountants have stated in their report included in our annual report on SEC Form 10-K filed with the Securities and Exchange Commission on March 31, 2009 and as amended on April 30, 2009 that we have incurred a net loss and negative cash flows from operations of \$5,807,353 and \$4,769,496, respectively, for the year ended December 31, 2008. This loss, in addition to a lack of operational history, raises substantial doubt about our ability to continue as a going concern. We currently have sufficient working capital to fund operations through December 2009. In the absence of significant revenue and profits, and since we do not expect to generate significant revenues in the foreseeable future, we, in order to fund future operations, 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 2009. 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.

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 continue our research and development efforts on our early, pre-clinical stage products and build out our corporate infrastructure.

## Plan of Operations

We expect to continue to incur operating losses for the foreseeable future, primarily due to our continued research and development activities attributable to Radilex, Viprovex and any other proposed product, if any, derived from Homspera and general and administrative activities.

The preliminary results of our pre-clinical studies using Homspera, Radilex and Viprovex may not be indicative of results that will be obtained from subsequent studies or from more extensive trials. Further, our pre-clinical or clinical trials may not be successful, and we may not be able to obtain the required regulatory approvals in a timely fashion, or at all.

## Product Research and Development

We incurred expenses of \$134,164 and \$482,584 for the three and nine month periods ended September 30, 2009 in research and development activities related to the development of Homspera, Radilex and Viprovex versus expenses of \$361,773 and \$788,145 for the three and nine months ended September 30, 2008. From our inception in October 2002, we have spent \$3,339,301 on research and development activities. These costs only include the manufacture and delivery of our drug by third party manufacturers and payments to contract research organizations and consultants for consulting related to our studies and costs of performing such studies. Significant costs relating to research and development, such as compensation for Dr. Siegel, have been classified in officers' salaries for consistency of financial reporting.

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We anticipate that during the next 12 months we will decrease our research and development spending to a total of approximately \$500,000 in an effort to further develop Radilex and Viprovex. This research and development cost estimate includes additional animal pharmacology studies, formulation and animal safety/toxicity studies. If we receive additional funds, through investment funding, licensing agreements or grants, we expect we will increase our research and development spending above this level.

We believe that initial revenues, if any, will likely be generated through partnerships, alliances and/or licensing agreements with pharmaceutical or biotechnology companies. Our focus during the next 12 months will be to identify those companies which we believe may have an interest in our proposed products and attempt to negotiate arrangements for potential partnerships, alliances and/or licensing arrangements. Alliances between pharmaceutical and biotechnology companies can take a variety of organizational forms and involve many different payment structures such as upfront payments, milestone payments, equity injections and royalty payments. To date, we have not entered into discussions with and have no agreements or arrangements with any such companies. Even if we are successful in entering into such a partnership or alliance or licensing our technology, we anticipate that the earliest we may begin to generate revenues from operations would be calendar year 2010. There is no assurance that we will ever be successful in reaching such agreements or ever generate revenues from operations.

We will need to generate significant revenues from product sales and or related royalties and license agreements to achieve and maintain profitability. Through September 30, 2009, 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 potential products or technologies.

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 our potential products, if any. 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.

If we are successful in achieving desirable results for these applications, we intend to design the protocols and begin further studies for this and other applications, 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 for these indications 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.

If we are successful in completing our studies and the results are as we anticipate, we intend to prepare and submit the necessary documentation to the FDA and other regulatory agencies for approval. If approval for Homspera, Radilex and/or Viprovex is granted, we expect to begin efforts to commercialize our product, if any, immediately thereafter, however, since we are currently in the pre-clinical stage of development, it will take an indeterminate amount of time in development before we have a marketable drug, if ever.

**Off-Balance Sheet Arrangements** 

There were no off-balance sheet arrangements as of September 30, 2009.

Liquidity and Capital Resources

At September 30, 2009, we had current assets of \$868,996 consisting of cash and cash equivalents of \$786,834, and prepaid assets and other current assets of \$82,162. Also, at September 30, 2009, we had current liabilities of \$2,453,366 consisting of accounts payable and accrued liabilities of \$728,366, notes payable of \$1,500,000 and redemption option liability of \$225,000. This resulted in working capital deficit of \$1,584,370. During the nine months ended September 30, 2009 and 2008, we used cash in operating activities of \$2,369,892 and \$3,735,098, respectively. From the date of inception (October 30, 2002) to September 30, 2009, we had a net loss of \$28,490,998 and used cash of \$15,589,368 in operating activities. We met our cash requirements from our inception (October 30, 2002) through September 30, 2009 via the private placement of \$7,889,151 of our common stock and \$8,573,628 from the issuance of notes payable, net of repayments.

We currently have no revenue. There is no guarantee that our business model will be successful, or that we will be able to generate sufficient revenue to fund future operations. As a result, we expect our operations to continue to use net cash, and that we will be required to seek additional debt or equity financings during the coming quarters. Since inception, we have financed our operations through debt and equity financing. While we have raised capital to meet our working capital and financing needs in the past, additional financing is required in order to meet our current and projected cash flow deficits from operations and development of our product line.

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 2002 to September 30, 2009, we were able to obtain financing of \$17,557,526 from the private placements of our securities (which resulted in net proceeds to us of \$16,462,779). In January 2008 we sold \$2 million in secured convertible debentures which resulted in net proceeds to us of \$1,815,000. In June 2008 we sold an additional \$1 million of the secured convertible debentures as per the terms of the securities purchase agreement with YA Global Investments L.P. In August 2008 we sold \$5 million in secured convertible debentures to a group of funds managed by Brencourt Advisors LLP. Based on our current plan of operations all of our current funding is expected to be depleted by the end of December 2009. If we are not successful in generating sufficient liquidity from operations or in raising sufficient capital resources, it would have a material adverse effect on our business, results of operations, liquidity and financial condition.

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Our registered independent certified public accountants have stated in their report included in our annual report on SEC Form 10-K for the year ended December 31, 2008 filed with the Securities and Exchange Commission on March 31, 2009 that the Company's recurring losses and negative cash flow raise substantial doubt about the Company's ability to continue as a going concern.

While we have 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 potential 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.

During fiscal year 2009, we will pay our Chief Executive Officer, Chief Financial Officer and Chief Scientific Officer an aggregate of \$746,000 pursuant to their employment agreements.

We currently have \$8,868,889 in notes payable, of which \$1,500,000 is current and payable on December 31, 2009. An additional \$1,500,000 matures on December 31, 2010 and the remaining balance of \$5,868,889 will mature in 2013 and beyond.

Until such time, if at all, as we receive adequate funding, we intend to continue to defer payment of all of our obligations which are capable of being deferred, which actions have resulted in some vendors demanding cash payment for their goods and services in advance, and other vendors refusing to continue to do business with us. 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 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. Based on our operating expenses and anticipated research and development activities we believe we have sufficient capital to meet our operating needs through December 2009. Thereafter, we believe that we will require an additional \$3,500,000 to meet our expenses over the next 12 months.

Acquisition or Disposition of Plant and Equipment

We did not dispose or acquire any significant property, plant or equipment during the quarter ended September 30, 2009. We do not anticipate the sale of any significant property, plant or equipment during the next twelve months.

Inflation

We do not believe that inflation has had a material effect on our business, financial condition or results of operations.

**Off-Balance Sheet Arrangements** 

There were no off-balance sheet arrangements as of September 30, 2009.

Critical Accounting Policies and Estimates

The preparation of our consolidated unaudited condensed consolidated financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and judgments that affect our reported assets, liabilities, revenues, and expenses, and the disclosure of contingent assets and liabilities.

We describe our significant accounting policies in the Notes to Consolidated Financial Statements included in our Annual Report on SEC Form 10-K filed with the Securities and Exchange Commission. We discuss our critical accounting policies and estimates in Management's Discussion and Analysis of Financial Condition and or Plan of Operation in SEC Form 10-K. Except for the below accounting for Derivative Instruments and Hedging, and any other accounting as indicated in this quarterly report, there have been no material revisions to the critical accounting policies as filed in our Annual Report on Form 10-K as of and for the year ended December 31, 2008 with the SEC on March 31, 2009 and as amended on April 30, 2009.

#### Accounting for Derivative Instruments and Hedging

In June 2008, the FASB issued new accounting guidance which requires entities to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock by assessing the instrument's contingent exercise provisions and settlement provisions. The effect of this guidance is described in Note 5 to unaudited condensed consolidated financial statements, September 30, 2009.

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#### Recent Accounting Pronouncements

For information regarding other recent accounting pronouncements and their effect on the Company, see "Recent Accounting Pronouncements" in Note 1 of the Unaudited Notes to Condensed Consolidated Financial Statements contained herein.

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable to smaller reporting companies.

## ITEM 4. CONTROLS AND PROCEDURES

#### Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file under the Exchange Act is accumulated and communicated to our management, including our principal executive and financial officers, as appropriate to allow timely decisions regarding required disclosure.

As of the end of the period covered by this Quarterly Report on form 10-Q, our management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial (and principal accounting) Officer, carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act). Based upon that evaluation and due to the material weakness existing in our internal controls as of December 31, 2008 (described below) which has not been fully remediated as of September 30, 2009, we have concluded that as of September 30, 2009, our disclosure controls and procedures were ineffective.

#### Changes in internal controls.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. Material weaknesses would permit information required to be disclosed by the Company in the reports that it files or submits to not be recorded, processed, summarized and reported, within the time periods specified in the Securities Exchange Commission's rules and forms. In our Annual Report on Form 10-K for the year ended December 31, 2008, we identified a material weakness consisting of limited resources and a limited number of employees, namely, an understaffed financial and accounting function, and the need for additional personnel to prepare and analyze financial information in a timely manner and to allow review and on-going monitoring and enhancement of our controls.

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During the three months ending September 30, 2009 we continued to evaluate our internal control documentation. Although we made progress towards remediation of the deficiencies giving rise to the material weakness, we are unable to conclude that the material weakness described above was remediated as of September 30, 2009.

There were no changes in our internal controls over financial reporting during the quarter ended September 30, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### Limitations on Effectiveness of Controls and Procedures

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include, but are not limited to, the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

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#### PART II - OTHER INFORMATION

## ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

## ITEM 1A. RISK FACTORS

Not required for smaller reporting companies.

## ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Convertible Debentures Sold For Accrued Interest

Note Issued To YA Global Investments, L.P. For Accrued Interest

On September 30, 2009, per the terms of the amended Securities Purchase Agreement with YA Global Investments L.P., the Company issued two 0% interest convertible debentures with a five year term of exercise and a conversion price of \$0.34 per share, subject to adjustment, as payment of an aggregate of \$75,000 in interest accrued during the three months ended September 30, 2009. The securities were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

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Note Issued To Funds Managed by Brencourt Advisors, LLC For Accrued Interest

On September 30, 2009, per the terms of the amended Securities Purchase Agreement with Funds Managed by Brencourt Advisors, LLC the Company issued four 0% interest convertible debentures with a five year term of exercise and a conversion price of \$0.34 per share, subject to adjustment, as payment of an aggregate of \$125,000 in interest accrued during the three months ended September 30, 2009. The securities were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act of 1933, as amended, and Rule 506 promulgated thereunder.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITIES HOLDERS

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

- 31.1 <u>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.</u>
- 31.2 <u>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.</u>
- 32.1 <u>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.\*</u>
- 32.2 <u>Certifications of Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as</u> adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.\*

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

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## Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on November 16, 2009.

IR BioSciences Holdings, Inc.

By: /s/ Michael K. Wilhelm

Michael K. Wilhelm

President, Chief Executive Officer

/s/ John N. Fermanis John N. Fermanis Chief Financial Officer

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