

INVIVO THERAPEUTICS HOLDINGS CORP.

Form 10-Q

November 13, 2012

[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 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, 2012.

or

.. **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from            to            .

Commission File Number: 000-52089

**InVivo Therapeutics Holdings Corp.**

(Exact name of registrant as specified in its charter)

Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form 10-Q

<b>Nevada</b> (State or other jurisdiction of incorporation or organization)	<b>36-4528166</b> (I.R.S. Employer Identification Number)
<b>One Kendall Square</b>  <b>Suite B14402</b>  <b>Cambridge, MA</b> (Address of principal executive offices)	<b>02139</b> (Zip code)
<b>(617) 863-5500</b> (Registrant's telephone number, including area code)	

Indicate by check mark whether the 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 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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  No

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.

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input checked="" type="checkbox"/>

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

As of November 9, 2012, 65,852,992 shares of the registrant's Common Stock \$0.00001 par value, were issued and outstanding.

**Table of Contents**

**INVIVO THERAPEUTICS HOLDINGS CORP.**

**Quarterly Report on Form 10-Q for the period ended September 30, 2012**

**TABLE OF CONTENTS**

**PART I**

**FINANCIAL INFORMATION**

Item	Page
<b><u>1. Financial Statements</u></b>	
<u>Consolidated Balance Sheets as of September 30, 2012 and December 31, 2011</u>	3
<u>Consolidated Statements of Operations for the three and nine months ended September 30, 2012 and 2011</u>	4
<u>Consolidated Statements of Cash Flows for the nine months ended September 30, 2012 and 2011</u>	5
<u>Notes to Financial Statements (Unaudited)</u>	7
<b><u>2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	16
<b><u>3. Quantitative and Qualitative Disclosures about Market Risk</u></b>	18
<b><u>4. Controls and Procedures</u></b>	18

**PART II**

**OTHER INFORMATION**

<b><u>1. Legal Proceedings</u></b>	19
<b><u>1A. Risk Factors</u></b>	19
<b><u>2. Unregistered Sales of Equity Securities and Use of Proceeds</u></b>	19
<b><u>3. Defaults Upon Senior Securities</u></b>	19
<b><u>4. Mine Safety Disclosures</u></b>	19
<b><u>5. Other Information</u></b>	19
<b><u>6. Exhibits</u></b>	19

**Table of Contents****PART I FINANCIAL INFORMATION****Item 1. Financial Statements.****InVivo Therapeutics Holdings Corp.****(A Developmental Stage Company)****Consolidated Balance Sheets**

	September 30, 2012 Unaudited	As of December 31, 2011
<b>ASSETS:</b>		
Current assets:		
Cash and cash equivalents	\$ 15,549,609	\$ 4,363,712
Restricted cash	634,750	547,883
Prepaid expenses	126,259	104,022
Total current assets	16,310,618	5,015,617
Property and equipment, net	2,024,524	520,482
Other assets	153,014	166,139
Total assets	\$ 18,488,156	\$ 5,702,238
<b>LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 1,141,267	\$ 567,195
Loan payable-current portion	106,911	50,578
Capital lease payable-current portion	37,353	30,724
Derivative warrant liability	10,800,855	35,473,230
Accrued expenses	761,939	618,369
Total current liabilities	12,848,325	36,740,096
Loan payable-less current portion	139,750	83,794
Capital lease payable-less current portion	11,119	38,042
Total liabilities	12,999,194	36,861,932
Commitments and contingencies		
Stockholders' equity (deficit)		
Common stock, \$0.00001 par value, authorized 200,000,000 shares at September 30, 2012 and December 31, 2011; issued and outstanding 65,635,400 and 53,760,471 shares at September 30, 2012 and December 31, 2011, respectively.	656	538
Additional paid-in capital	39,925,749	16,656,830
Deficit accumulated during the development stage	(34,437,443)	(47,817,062)
Total stockholders' equity (deficit)	5,488,962	(31,159,694)

Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form 10-Q

Total liabilities and stockholders' equity (deficit)	\$ 18,488,156	\$ 5,702,238
--	---------------	--------------

See notes to the consolidated financial statements.

**Table of Contents****InVivo Therapeutics Holdings Corp.****(A Developmental Stage Company)****Consolidated Statements of Operations****(Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from November 28, 2005 (inception) to September 30, 2012
	2012	2011	2012	2011	
Operating expenses:					
Research and development	\$ 1,374,852	\$ 1,016,865	\$ 3,622,800	\$ 3,045,426	\$ 12,506,634
General and administrative	1,466,049	1,196,455	4,433,929	3,095,877	12,685,466
Total operating expenses	2,840,901	2,213,320	8,056,729	6,141,303	25,192,100
Operating loss	(2,840,901)	(2,213,320)	(8,056,729)	(6,141,303)	(25,192,100)
Other income (expense):					
Other income					383,000
Interest income	13,061	4,778	27,842	7,539	47,891
Interest expense	(12,454)		(28,147)	(7,150)	(1,094,478)
Derivatives gain (loss)	10,869,209	5,275,591	21,436,653	6,559,835	(8,581,508)
Other income	10,869,816	5,280,369	21,436,348	6,560,224	(9,245,095)
Net income (loss)	\$ 8,028,915	\$ 3,067,049	\$ 13,379,619	\$ 418,921	\$ (34,437,195)
Net income (loss) per share, basic	\$ 0.12	\$ 0.06	\$ 0.21	\$ 0.01	\$ (1.01)
Net income (loss) per share, diluted	\$ 0.11	\$ 0.06	\$ 0.19	\$ 0.01	\$ (1.01)
Weighted average number of common shares outstanding, basic	65,109,037	51,889,111	62,357,300	51,743,138	34,226,324
Weighted average number of common shares outstanding, diluted	74,157,957	54,269,856	71,734,784	54,198,981	34,226,324

See notes to the consolidated financial statements.

**Table of Contents****InVivo Therapeutics Holdings Corp.****(A Developmental Stage Company)****Consolidated Statements of Cash Flows****(Unaudited)**

	Nine Months Ended September 30,		Period from November 28, 2005 (inception) to September 30, 2012
	2012	2011	
<b>Cash flows from operating activities:</b>			
Net income (loss)	\$ 13,379,619	\$ 418,921	\$ (34,437,195)
<b>Adjustments to reconcile net income (loss) to net cash used in operating activities:</b>			
Depreciation and amortization expense	218,579	101,599	456,206
Non-cash derivatives (gain) losses	(21,436,653)	(6,559,835)	8,581,508
Non-cash interest expense			962,834
Common stock issued to 401(k) plan	60,906		102,568
Common stock issued for services	24,750	200,676	234,201
Share-based compensation expense	823,617	622,141	2,623,969
<b>Changes in operating assets and liabilities:</b>			
Restricted cash	(86,867)	(155,000)	(634,750)
Prepaid expenses	(22,237)	(28,306)	(116,208)
Other assets		(75,000)	(200,000)
Accounts payable	574,072	216,862	1,141,267
Accrued interest payable			(15,256)
Accrued expenses	143,570	111,534	761,939
<b>Net cash used in operating activities</b>	<b>(6,320,644)</b>	<b>(5,146,408)</b>	<b>(20,538,917)</b>
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(1,709,496)	(241,995)	(2,340,204)
<b>Net cash used in investing activities</b>	<b>(1,709,496)</b>	<b>(241,995)</b>	<b>(2,340,204)</b>
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of convertible notes payable			4,181,000
Proceeds from convertible bridge notes			500,000
Principal payments on capital lease obligation	(20,294)	118,057	(45,068)
Proceeds from (repayment of) loans payable	112,289	(17,353)	246,661
Proceeds from issuance of common stock and warrants	19,124,042	10,434	33,546,137
<b>Net cash provided by financing activities</b>	<b>19,216,037</b>	<b>111,138</b>	<b>38,428,730</b>
Increase (decrease) in cash and cash equivalents	11,185,897	(5,277,265)	15,549,609
Cash and cash equivalents at beginning of period	4,363,712	8,964,194	
<b>Cash and cash equivalents at end of period</b>	<b>\$ 15,549,609</b>	<b>\$ 3,686,929</b>	<b>\$ 15,549,609</b>

(continued)

See notes to the consolidated financial statements.



**Table of Contents****InVivo Therapeutics Holdings Corp.****(A Developmental Stage Company)****Consolidated Statements of Cash Flows (Concluded)****(Unaudited)**

	<b>Nine Months Ended, September 30,</b>		<b>Period from November 28, 2005 (inception) to September 30, 2012</b>
	<b>2012</b>	<b>2011</b>	
<b>Supplemental disclosure of cash flow information and non-cash transactions:</b>			
Cash paid for interest	\$ 22,272	\$ 5,077	\$ 128,319
Conversion of convertible notes payable and accrued interest into common stock	\$	\$	\$ 4,672,484
Conversion of convertible bridge note payable and accrued interest into common stock	\$	\$	\$ 504,597
Asset acquired through capital lease obligation	\$	\$ 93,540	\$ 93,540
Beneficial conversion feature on convertible and bridge notes payable	\$	\$	\$ 134,410
Fair value of warrants issued with bridge notes payable	\$	\$	\$ 178,727
Fair value of warrants issued in connection with loan agreement	\$	\$ 10,051	\$ 10,051
Issuance of founders shares	\$	\$	\$ 248
Reclassification of derivative warrant liability to additional paid-in capital	\$ 3,235,722	\$	\$ 4,475,261

See notes to the consolidated financial statements.

---

**Table of Contents**

**InVivo Therapeutics Holdings Corp.**

**(A Development Stage Company)**

**Notes to Consolidated Financial Statements**

**Period Ended September 30, 2012 (Unaudited)**

**1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION**

***Business***

InVivo Therapeutics Corporation ( InVivo ) was incorporated on November 28, 2005 under the laws of the State of Delaware. InVivo is developing and commercializing biopolymer scaffolding devices for the treatment of spinal cord injuries and peripheral nerve injuries. In spinal cord injuries, the biopolymer devices are designed to protect the damaged spinal cord from further secondary injury and promote neuroplasticity, a process where functional recovery can occur through the rerouting of signaling pathways to the spared healthy tissue.

Since its inception, InVivo has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. Accordingly, InVivo is considered to be in the development stage.

***Reverse Merger***

On October 26, 2010, InVivo completed a reverse merger transaction (the Merger ) with InVivo Therapeutics Holdings Corp. (formerly Design Source, Inc.) ( ITHC ), a publicly traded company incorporated under the laws of the State of Nevada. InVivo became a wholly owned subsidiary of ITHC, which continues to operate the business of InVivo. As part of the Merger, ITHC issued 31,147,190 shares of its Common Stock to the holders of InVivo common stock on October 26, 2011 in exchange for the 2,261,862 outstanding common shares of InVivo and also issued 500,000 shares to its legal counsel in consideration for legal services provided. All share and per share amounts presented in these consolidated financial statements have been retroactively restated to reflect the 13.7706 exchange ratio of InVivo shares for ITHC shares in the Merger. Immediately prior to the Merger, ITHC had 6,999,981 shares of Common Stock outstanding.

The Merger was accounted for as a reverse merger, and InVivo is deemed to be the accounting acquirer. The Merger was recorded as a reverse recapitalization, equivalent to the issuance of common stock by InVivo for the net monetary assets of ITHC accompanied by a recapitalization. At the date of the Merger, the 6,999,981 outstanding ITHC shares were reflected as an issuance of InVivo common stock to the prior shareholders of ITHC. ITHC had no net monetary assets as of the Merger so this issuance was recorded as a reclassification between additional paid-in capital and par value of Common Stock.

The historical consolidated financial statements are those of InVivo as the accounting acquirer. The post-merger combination of ITHC and InVivo is referred to throughout these notes to consolidated financial statements as the Company. Subsequent to the Merger, the Company completed three closings as part of a private placement.

On October 26, 2010, in connection with the Merger described above, ITHC transferred all of its operating assets and liabilities to its wholly-owned subsidiary, D Source Split Corp., a company organized under the laws of Nevada ( DSSC ). DSSC was then split-off from ITHC through the sale of all outstanding shares of DSSC (the Split-Off ). The assets and liabilities of ITHC were transferred to the Split-Off Shareholders in the Split-Off. ITHC executed a split off agreement with the Split-Off Shareholders which obligates the Split-Off Shareholders to assume all prior liabilities associated with Design Source, Inc. and all DSSC liabilities. In conjunction with the Split-Off, certain shareholders of ITHC surrendered for cancellation shares of ITHC common stock for no additional consideration. The purpose of the Split-Off was to make ITHC a shell company with no assets or liabilities in order to facilitate the Merger. Although all transactions related to the Merger occurred simultaneously, the Split-Off, including the cancellation of shares, was considered to have occurred immediately prior to the Merger for accounting purposes. As the accounting acquiree in a reverse merger with a shell company, the historical financial statements of ITHC are not presented and these ITHC transactions are not reflected in the Company s accompanying consolidated financial statements.

***Basis of Presentation***

## Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form 10-Q

The accompanying unaudited consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States ( GAAP ) consistent with those applied in, and should be read in conjunction with, the Company's audited financial statements and related footnotes for the year ended December 31, 2011 included in the Company's Annual Report on Form 10-K as filed with the United States Securities and Exchange Commission ( SEC ) on March 15, 2012. The unaudited consolidated financial statements reflect all adjustments, consisting only of normal recurring adjustments, which are, in the opinion of management, necessary for a fair presentation of the Company's financial position as of September 30, 2012 and its results of operations and cash flows for the interim periods presented and are not necessarily indicative of results for subsequent interim periods or for the full year. The interim financial statements do not include all of the information and footnotes required by GAAP for complete financial statements as allowed by the relevant SEC rules and regulations; however, the Company believes that its disclosures are adequate to ensure that the information presented is not misleading.

**Table of Contents****2. CASH AND CASH EQUIVALENTS**

As of September 30, 2012, the Company held \$15,550,000 in cash and cash equivalents. From time to time, the Company may have cash balances in financial institutions in excess of insurance limits. The Company has never experienced any losses related to these balances. All of the Company's non-interest bearing cash balances were fully insured at September 30, 2012 due to a temporary federal program through December 31, 2012. Under the program, there is no limit on the amount of insurance for eligible accounts. Beginning in 2013, insurance coverage will revert to \$250,000 per depositor at each financial institution, and non-interest bearing cash balances may again exceed federally insured limits. The Company's cash equivalents are in money market funds and certificates of deposit. Cash and cash equivalents consist of the following:

	September 30, 2012	December 31, 2011
Cash on hand	\$ 157,202	\$ 133,035
Money market fund	10,392,407	4,230,677
Certificates of deposit maturing in November 2012	5,000,000	
Total cash and cash equivalents	\$ 15,549,609	\$ 4,363,712

**3. RESTRICTED CASH**

Restricted cash of \$635,000 represents \$340,000 of security deposits related to the Company's credit card account and loan payable (see Note 7), and a \$295,000 cash account securing a standby letter of credit in favor of a landlord (see Note 5). This letter of credit expires December 22, 2012 and may be extended through July 31, 2023.

**4. FAIR VALUE OF ASSETS AND LIABILITIES**

The Company groups its assets and liabilities generally measured at fair value in three levels, based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value.

Level 1 Valuation is based on quoted prices in active markets for identical assets or liabilities. Level 1 assets and liabilities generally include debt and equity securities that are traded in an active exchange market. Valuations are obtained from readily available pricing sources for market transactions involving identical assets or liabilities.

Level 2 Valuation is based on observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Valuation is based on unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation.

The Company uses valuation methods and assumptions that consider among other factors the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants considered to be derivative instruments.

**Table of Contents**

Assets and liabilities measured at fair value on a recurring basis are summarized below:

	September 30, 2012			Fair Value
	Level 1	Level 2	Level 3	
<b>Liabilities:</b>				
Derivative warrant liability	\$	\$ 10,800,855	\$	\$ 10,800,855

	December 31, 2011			Fair Value
	Level 1	Level 2	Level 3	
<b>Liabilities:</b>				
Derivative warrant liability	\$	\$ 35,473,230	\$	\$ 35,473,230

**5. COMMITMENTS*****Operating Lease Commitment***

The Company leases approximately 1,597 square feet of laboratory and office space in Medford, Massachusetts at a monthly cost of \$5,476 under a lease expiring on November 15, 2012.

On November 29, 2011 and as amended on September 17, 2012, the Company entered into a commercial lease for 26,150 square feet of office, laboratory and manufacturing space in Cambridge, MA ( Cambridge Lease ). The term of this lease is six years and three months, with one five-year extension option. The terms of the initial lease required a standby letter of credit in the amount of \$295,000 secured by a deposit with a commercial bank (see Note 3).

The Cambridge Lease contains rent holidays and rent escalation clauses. The Company recognizes rent expense on a straight-line basis over the lease term and record the difference between the amount charged to expense and the rent paid as a deferred rent liability. As of September 30, 2012, the amount of deferred rent liability is \$244,000 and is included in Accrued expenses.

It is the Company's policy to assess whether improvements made to the space rented under operating leases should be accounted for as lessor or lessee assets. If the landlord/lessor makes the improvements and presents us with the finished space on a turnkey basis, we view the assets as being lessor assets. When the Company does the remodeling work and receives an allowance that may or may not cover all the costs, the Company makes a judgment as to the classification between lessor and lessee assets. The Company considers an asset to be a lessor asset if all of the following criteria are met:

the lease specifically requires the lessee to make the improvement,

the improvement is fairly generic,

the improvement increases the fair value of the property to the lessor, and

the useful life of the improvement is longer than our lease term.

If any of the above criteria are not met, the Company considers the assets to be lessee assets, which are recorded as leasehold improvements in the balance sheet and payments received from the lessor to fund any portion of the cost of lessee assets are accounted for as lease incentives. Assets considered to be lessor assets are not reflected in the Company's Consolidated Balance Sheets. To the extent that the Company paid for

## Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form 10-Q

such lessor assets and was not reimbursed through construction allowances, such net payments are recorded as leasehold improvements, which are amortized to rent expense over the lease term. As of September 30, 2012, such leasehold improvements totaled \$266,000.

**Table of Contents**

Pursuant to the terms of the non-cancelable lease agreements in effect at September 30, 2012, future minimum rent commitments are as follows:

<b>Year Ended December 31,</b>	
2012	\$ 250,550
2013	1,168,659
2014	1,198,265
2015	1,237,533
2016	1,263,642
2017 and thereafter	2,327,367
<b>Total</b>	<b>\$ 7,446,016</b>

Total rent expense for the nine months ended September 30, 2012 and 2011 including month-to-month leases, was \$433,000 and \$267,000, respectively. Total rent expense for the three ended September 30, 2012 and 2011 including month-to-month leases, was \$218,000 and \$88,000, respectively.

**Other Commitments**

In January 2012, the Company entered into a research contract with the Geisenger Health System under which the Company is obligated to pay Geisenger \$150,000 for a pre-clinical study that will evaluate the Company's hydrogel for the treatment of peripheral nerve injuries. During the first quarter of 2012, the Company made an up-front payment of \$60,000 for this study and expensed this cost to Research and Development. During the second and third quarters of 2012, the Company did not make any payments under this contract.

**6. CAPITAL LEASE PAYABLE**

In February 2011, the Company entered into a capital lease agreement under which the Company leased certain laboratory equipment. Capital lease obligations consisted of the following:

	<b>2012</b>	<b>2011</b>
Capital lease payable	\$ 48,472	\$ 68,766
Less:current portion	(37,353)	(30,724)
	<b>\$ 11,119</b>	<b>\$ 38,042</b>

The total value of the laboratory equipment acquired under this capital lease agreement was \$124,151 including a down payment of approximately \$31,000. The capital lease is payable in monthly installments of \$2,812 payable over thirty six months with the final payment due in January 2014. For the three and nine months ended September 30, 2012, interest expense recorded on the capital lease was \$480 and \$3,024 respectively. For the three and nine months ended September 30, 2011, interest expense recorded on the capital lease was \$949 and \$2,973, respectively. For the three and nine months ended September 30, 2012 depreciation expense was \$6,208 and \$18,624, respectively. For the three and nine months ended September 30, 2011 depreciation expense was \$6,208 and \$16,664, respectively.

**Table of Contents****7. LOAN PAYABLE**

In June 2011, the Company entered into a loan agreement with a bank. The loan agreement provided the Company with a \$1,000,000 line of credit for the purchase of capital equipment. The line was available to the Company until December 31, 2012. The annual interest rate is the greater of 6.75% or 3.50% above the Prime Rate. Borrowings are repayable in equal monthly installments over a thirty six month period. The Company was assessed commitment fees totaling \$10,000 and issued the bank a warrant for the purchase of 16,071 shares of Common Stock. The warrant has a seven year term and is exercisable at \$1.40 per share. The fair value of the warrant was determined to be approximately \$10,000 and was recorded as a deferred financing cost and has been amortized to interest expense over a three year period commencing from the date of the first draw from the equipment line of credit. Amortization of the deferred financing costs for the nine ended September 30, 2012 was \$5,875 and is included in interest expense. As of September 30, 2012, advances under the equipment line of credit totaled \$320,733. The equipment line of credit was secured by substantially all the assets of the Company excluding intellectual property. In accordance with the agreement, the Company was required to maintain its primary banking and investments accounts with the commercial bank and a deposit of not less than \$50,000 at the bank. Loan payable consisted of the following:

	September 30, 2012	December 31, 2011
Equipment loan	\$ 246,661	\$ 134,372
Less: current portion	(106,911)	(50,578)
	\$ 139,750	\$ 83,794

Interest expense related to the loan payable for the three and nine months ended September 30, 2012 totaled \$3,694 and \$8,895, respectively.

In October 2012, the Company entered into a \$2 million loan facility with Mass Development Finance Agency and under terms of this agreement the Company repaid the \$247,000 outstanding loan balance due to the bank (see Note 12). In September 2012, The Company paid a \$15,000 commitment fee to the Mass Development Finance Agency and \$10,000 was charged to interest expense.

**8. COMMON STOCK**

The Company has authorized 200,000,000 shares of Common Stock, \$0.00001 par value per share, of which 65,635,400, shares were issued and outstanding as of September 30, 2012 and 53,760,471 shares were issued and outstanding as of December 31, 2011.

In February 2012, the Company completed a public offering of Common Stock and issued 9,523,810 shares of Common Stock at a purchase price of \$2.10 per common share. The offering raised gross proceeds of 20 million and the Company received net proceeds of \$18,207,000 after deducting underwriter discounts and offering expenses.

During the nine months ended September 30, 2012, the Company issued 687,428 shares of Common Stock upon the exercise of stock options and received cash proceeds of approximately \$50,000.

During the nine months ended September 30, 2012, the Company issued 1,619,183 shares of Common Stock upon the exercise of warrants, including warrants to purchase 1,837,969 shares of Common Stock exercised through cashless exercise provisions and warrants to purchase 702,946 shares of Common Stock exercised for cash, providing cash proceeds of \$919,000.

During the nine months ended September 30, 2012, the Company issued 930,332 shares of Common Stock upon the exercise of warrants, including warrants to purchase 1,478,871 shares of Common Stock exercised through cashless exercise provisions and warrants to purchase 205,000 shares of Common Stock exercised for cash, providing cash proceeds of \$253,000.

During the nine months ended September 30, 2012, the Company issued 29,508 shares of common stock with a fair value of \$61,000 to the Company's 401(k) plan as a matching contribution.



**Table of Contents****9. DERIVATIVE INSTRUMENTS**

Certain warrants issued to the investors in the fourth quarter of 2010 have provisions that include anti-dilution protection and, under certain conditions, grant the right to the holder to request the Company to repurchase the warrant. Accordingly, these warrants are accounted for as a derivative liability on the consolidated balance sheet and measured at fair value. The Company uses the Black-Scholes option pricing model and assumptions that consider among other factors the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants considered to be derivative instruments. The fair value of these derivative instruments at September 30, 2012 and December 31, 2011 was \$10,800,855 and \$35,473,230, respectively, and are included as a derivative warrant liability, a current liability. Changes in fair value of the derivative financial instruments are recognized currently in the consolidated statement of operations as a derivatives gain or loss. The warrant derivative gains or losses are non-cash items and are included in other income in the consolidated statements of operations. The warrant derivative gains for the three months and nine months ended September 30, 2012 was \$10,869,209 and \$21,436,653, respectively. The warrant derivative gains for the three months and nine months ended September 30, 2011 was \$5,275,591 and \$6,559,835, respectively. The assumptions used principally in determining the fair value of warrants were as follows:

	<b>September 30, 2012</b>
Risk-free interest rate	0.30%-0.34%
Expected dividend yield	0%
Expected term	2.92-3.18 years
Expected volatility	60.3%

The primary underlying risk exposure pertaining to the warrants is the change in fair value of the underlying Common Stock for each reporting period. The table below presents the changes in derivative warrant liability for the nine months ended September 30, 2012 and 2011:

	<b>Nine Months Ended September 30,</b>	
	<b>2012</b>	<b>2011</b>
Balance at December 31,	\$ 35,473,230	\$ 10,647,190
Decrease in the fair value of the warrants	(21,436,653)	(6,559,835)
Reduction in derivative liability due to exercise of warrants	(3,235,722)	
Balance at September 30,	\$ 10,800,855	\$ 4,087,355

**Table of Contents****10. STOCK OPTIONS**

In 2007, the Company adopted the 2007 Employee, Director and Consultant Stock Plan (the "2007 Plan"). Pursuant to the 2007 Plan, the Company's Board of Directors (or committees and/or executive officers delegated by the Board of Directors) may grant incentive and nonqualified stock options to the Company's employees, officers, directors, consultants and advisors. As of September 30, 2012, there were options to purchase an aggregate of 3,691,577 shares of Common Stock outstanding under the 2007 Plan and no shares available for future grants under the 2007 Plan.

On October 26, 2010, the Company's Board of Directors adopted the 2010 Equity Incentive Plan, (the "2010 Plan"). The Company's shareholders approved the 2010 Plan, as amended, on August 3, 2011 and on May 30, 2012 approved an amendment to the 2010 plan to increase the number of shares available under the 2010 Plan. The 2010 Plan provides for grants of incentive stock options to employees and nonqualified stock options and restricted Common Stock to employees, consultants and non-employee directors of the Company. As of September 30, 2012, the number of shares authorized for issuance under the 2010 Plan, as amended was 6,500,000 shares. As of September 30, 2012, there were options to purchase an aggregate of 2,917,616 shares of Common Stock outstanding under the 2010 Plan and 3,582,384 shares available for future grants under the 2010 Plan. Options issued under the 2007 Plan and the 2010 Plan (collectively the "Plans") are exercisable for up to 10 years from the date of issuance.

***Share-based compensation***

For stock options issued and outstanding for the three and nine months ended September 30, 2012 the Company recorded non-cash, stock-based compensation expense of \$55,659 and \$823,617, respectively, net of forfeitures.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model that uses the assumptions noted in the following table. Due to its limited operating history and limited number of sales of its Common Stock, the Company estimated its volatility in consideration of a number of factors including the volatility of comparable public companies. The Company uses historical data, as well as subsequent events occurring prior to the issuance of the financial statements, to estimate option exercises and employee terminations within the valuation model. The expected term of options granted under the Plans, all of which qualify as "plain vanilla," is based on the average of the contractual term (generally 10 years) and the vesting period (generally 48 months). For non-employee options, the expected term is the contractual term. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option.

The assumptions used principally in determining the fair value of options granted to employees for the nine months ended September 30, 2012 were as follows:

	<b>September 30, 2012</b>
Risk-free interest rate	1.05%
Expected dividend yield	0%
Expected term (employee grants)	5.99
Expected volatility	71%

**Table of Contents**

A summary of option activity under the Plans and options granted to officers of the Company outside any plan as of September 30, 2012 and changes during the three months then ended is presented below:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2011	6,302,893	\$ 0.76		
Granted	2,336,000	\$ 2.49		
Forfeited	(1,342,272)	\$ 2.03		
Exercised	(687,428)	\$ 0.07		
Outstanding at September 30, 2012	6,609,193	\$ 1.19	7.53	\$ 4,365,898
Vested at September 30, 2012	3,633,252	\$ 0.64	6.40	\$ 3,651,483

The weighted average grant-date fair value of options granted during three months ended September 30, 2012 was \$1.38 per share. The total fair value of options that vested during the nine months ended September 30, 2012 was \$950,531. As of September 30, 2012, there was approximately \$2,568,000 of total unrecognized compensation expense, related to non-vested share-based compensation arrangements. The unrecognized compensation expense is estimated to be recognized over a period of three years at September 30, 2012.

In September 2011, the Company granted 80,000 shares of Common Stock under the 2010 Plan to a consultant as a restricted stock award with 30,000 shares vesting upon FDA clearance of an Investigational Device Exemption to permit the commencement of a human clinical trial and 50,000 shares vesting upon FDA approval of the Company's biopolymer scaffolding device to treat spinal cord injuries. The Company had previously determined that the vesting of the 30,000 shares was probable and the fair value of these shares at \$23,400 was being amortized over an eight month period from September 2011 through April 2012. In March of 2012, the contract with the consultant was terminated and the consultant had no vested right to the restricted stock, so accordingly, the \$11,700 of expense previously recorded was reversed in 2012.

**11. WARRANTS**

The following presents information about warrants to purchase Common Stock issued and outstanding at September 30, 2012:

Year Issued	Classification	Number of Warrants	Exercise Price	Date of Expiration
2010	Derivative	13,537,994	\$ 1.40	10/26/2015-12/3/2015
2010	Derivative	1,967,858	\$ 1.00	9/26/2015-12/3/2015
2011	Equity	16,071	\$ 1.40	6/17/2018
2011	Equity	343,137	\$ 3.06	12/21/2016
Total		15,865,060		
Weighted average exercise price			\$ 1.39	
Weighted average life in years				3.18



**Table of Contents**

**12. SUBSEQUENT EVENT**

In October 2012, the Company entered into a loan agreement with the Massachusetts Development Finance Agency ( MassDev ) from the Commonwealth of Massachusetts s Emerging Technology fund. The loan agreement provides the Company with a \$2,000,000 line of credit, with \$200,000 to be used for working capital purposes and the remainder of which is to be used for the purchase of capital equipment. The annual interest rate is fixed at 6.5% with interest payments only commencing on November 1, 2012 for the first thirty months and then equal interest and principal payments over the next fifty-four months with the final maturity on October 5, 2019. In September 2012, the Company was assessed commitment fees totaling \$15,000, of which approximately \$10,000 was charged to interest expense. In October 2012 as part of the commitment fee, the Company issued MassDev a warrant for the purchase of 36,145 shares of Common Stock. The warrant has a seven year term and is exercisable at \$1.66 per share. The equipment line of credit was secured by substantially all the assets of the Company excluding intellectual property. In October 2012, the Company drew on the line and received proceeds of \$1,144,000, including \$200,000 for working capital purposes and \$944,000 for capital equipment.

---

## **Table of Contents**

### **Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following management's discussion and analysis should be read in conjunction with the unaudited consolidated financial statements included in this report and with the Company's historical consolidated financial statements and the related notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2011 (the 2011 Annual Report). The management's discussion and analysis contains forward-looking statements of our plans, objectives, expectations and intentions that involve risks and uncertainties, including those we detailed under Risk Factors in Item 1A of our 2011 Annual Report. Any statements that are not statements of historical fact are forward-looking statements. When used, the words believe, plan, intend, anticipate, target, estimate, expect and the like, and/or future tense or conditional constructions ( will, may, could, should, etc.), or similar expressions, identify certain of these forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements in this quarterly report. The Company's actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors. The Company does not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this quarterly report.*

*The discussion and analysis of the Company's financial condition and results of operations are based on the Company's financial statements, which the Company has prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, the Company evaluates such estimates and judgments, including those described in greater detail below. The Company bases its estimates on historical experience and on various other factors that the Company believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.*

#### **Overview**

The Company is developing and commercializing biopolymer scaffolding devices for the treatment of spinal cord injuries and peripheral nerve injuries. For spinal cord injuries, the biopolymer devices are designed to protect the damaged spinal cord from further secondary injury and promote neuroplasticity, a process where functional recovery can occur through the rerouting of signaling pathways to the spared healthy tissue.

Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. Accordingly, the Company is considered to be in the development stage.

#### **Recent Developments**

On October 5, 2012, the Company entered into a loan agreement with the Massachusetts Development Finance Agency ( MassDev ) from the Commonwealth of Massachusetts's Emerging Technology fund. The loan agreement provides the Company with a \$2,000,000 line of credit, of which \$200,000 may be used for working capital purposes and the remainder of which may be used for the purchase of capital equipment. The annual interest rate is fixed at 6.5% with interest payments only commencing on November 1, 2012 for the first thirty months and then equal interest and principal payments over the next fifty-four months with the final maturity on October 5, 2019. The Company was assessed commitment fees totaling \$15,000 and issued MassDev a warrant for the purchase of 36,145 shares of Common Stock. The warrant has a seven year term and is exercisable at \$1.66 per share. Advances under the loan agreement are secured by substantially all the assets of the Company excluding intellectual property. In October 2012, the Company drew down \$1,144,000 of the line, using \$200,000 for working capital purposes and \$944,000 for capital equipment purchases.

#### **Critical Accounting Policies and Estimates**

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

On an ongoing basis, we evaluate our estimates and judgments for all assets and liabilities, including those related to stock-based compensation expense and the fair value determined for stock purchase warrants classified as derivative liabilities. We base our estimates and judgments on historical experience, current economic and industry conditions and on various other factors that are believed to be reasonable under the circumstances. This forms the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from

## Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form 10-Q

other sources. Actual results may differ from these estimates under different assumptions or conditions. There have been no changes in our critical accounting policies and estimates from our 2011 Annual Report.

## **Table of Contents**

We believe that full consideration has been given to all relevant circumstances that we may be subject to, and the consolidated financial statements accurately reflect our best estimate of the results of operations, financial position and cash flows for the periods presented.

### **Results of Operations**

#### *Comparison of the three months ended September 30, 2012 and 2011*

##### **Research and Development Expenses**

Research and development expenses consist primarily of payments to contract research and development companies and payroll. Research and development expenses increased by approximately \$358,000 to approximately \$1,375,000 for the three months ended September 30, 2012 from approximately \$1,017,000 for the three months ended September 30, 2011. The increase in expenses is primarily attributable to increased research and development activity and the resulting increase in compensation cost of \$324,000 due to both additional staffing and pay raises.

##### **General and Administrative Expenses**

General and administrative expenses consist primarily of payroll, rent and professional services. General and administrative expenses increased by approximately \$270,000 to approximately \$1,466,000 for the three months ended September 30, 2012 from approximately \$1,196,000 for the three months ended September 30, 2011. The increase in expenses is primarily attributable to an increase in compensation costs of \$179,000 due to additional staffing and pay raises, an increase of \$53,000 in legal costs, an increase of \$100,000 of recruiting and relocation costs, an increase of \$33,000 in travel and conference meeting costs, offset by a decrease of \$148,000 in investor relations costs.

##### **Interest Expense**

Interest expense increased by \$12,000 to approximately \$12,000 for the three months ended September 30, 2012. The increase in interest expense is mainly due to an increase in borrowing under the loan payable.

##### **Derivatives Gain**

Derivatives gain increased by \$5,593,000 to \$10,869,000 for the three months ended September 30, 2012 from \$5,276,000 for the three months ended September 30, 2011. The increase in this non-cash gain during the three months ended September 30, 2012 reflects the decrease in the fair value of derivative warrant liability due primarily to the decrease in the fair value of the underlying Common Stock.

#### *Comparison of the nine months ended September 30, 2012 and 2011*

##### **Research and Development Expenses**

Research and development expenses increased by approximately \$578,000 to approximately \$3,623,000 for the nine months ended September 30, 2012 from approximately \$3,045,000 for the nine months ended September 30, 2011. The increase in expenses is primarily attributable to increased research and development activity and the resulting an increase in compensation costs of \$637,000 due to both additional staffing and raises offset by a reduction in stock compensation expense of \$104,000.

##### **General and Administrative Expenses**

General and administrative expenses increased by approximately \$1,338,000 to approximately \$4,434,000 for the nine months ended September 30, 2012 from approximately \$3,096,000 for the nine months ended September 30, 2011. The increase in expenses is primarily attributable to an increase in compensation costs of \$424,000 due to additional staffing and raises, an increase of \$183,000 in legal costs, an increase of \$128,000 in recruiting and relocation costs, an increase of \$204,000 in travel and conference meeting costs, an increase of \$306,000 in stock compensation costs and an increase in rent and facilities costs of \$133,000.

##### **Interest expense**

Interest expense increased by \$21,000 to approximately \$28,000 for the nine months ended September 30, 2012 from approximately \$7,000 for the nine months ended September 30, 2011. The increase in interest expense is due to an increase in borrowing under the loan payable.





## **Table of Contents**

### **Derivatives Gain**

Derivatives gain increased by \$14,877,000 to \$21,437,000 for the nine months ended September 30, 2012 from \$6,560,000 for the nine months ended September 30, 2011. The increase in this non-cash gain for the nine months ended September 30, 2012 reflects the decrease in the fair value of derivative warrant liability due primarily to the decrease in the fair value of the underlying Common Stock.

### **Liquidity and Capital Resources**

Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. Accordingly, the Company is considered to be in the development stage.

Since inception, the Company has experienced negative cash flows from operations. The Company has financed its operations primarily through the sale of equity-related securities. At September 30, 2012, the deficit accumulated during the development stage was approximately \$34,437,000.

At September 30, 2012, we had total current assets of approximately \$16,311,000 and current liabilities of approximately \$12,848,000 resulting in a working capital of approximately \$3,462,000. At September 30, 2012, the Company had total assets of approximately \$18,488,000 and total liabilities of approximately \$12,999,000, resulting in a stockholders' equity of \$5,489,000.

Net cash used by operating activities for the nine months ended September 30, 2012 was approximately \$6,321,000. The operating loss used \$8,057,000, increases in accounts payable and accrued expenses provided \$718,000, non-cash stock share based compensation provided \$824,000 and depreciation and amortization provided \$219,000. Significant commitments that will require the use of cash in operating activities in future periods include obligations under operating leases. Gross committed lease obligations amount to \$7,446,000. Total commitments due for the remainder of fiscal 2012 under operating leases are approximately \$251,000.

Net cash used by investing activities for the nine months ended September 30 2012 totaled \$1,710,000 for purchases of capital equipment.

Net cash provided by financing activities was approximately \$19,216,000 for the nine months ended September 30, 2012, due mainly to approximately \$18,155,000 proceeds from a public offering. In addition, the Company received \$969,000 from the exercise of stock options and warrants and approximately \$112,000 from loans, net of repayments.

At September 30, 2012, the Company had cash of approximately \$15,550,000, which the Company expects to be sufficient to meet its operating and capital requirements into the first quarter of 2014. However, the Company will need to raise substantial additional capital in the future to complete clinical trials, obtain marketing approvals and commercialize its products, potentially through debt or equity financings. The sale of debt or equity securities may cause dilution to existing stockholders. Furthermore, there can be no assurance that we will be able to raise such funds if and when they are required. Failure to obtain future funding when needed or on acceptable terms would materially adversely affect our results of operations.

### **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements, including unrecorded derivative instruments that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. We have certain warrants and options outstanding but we do not expect to receive sufficient proceeds from the exercise of these instruments unless and until the trading price of our Common Stock is significantly greater than the applicable exercise prices of the options and warrants and mainly following any necessary registering of underlying securities.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

This information has been omitted as the Company qualifies as a smaller reporting company.

**Item 4. Controls and Procedures.**

**Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that the information required to be disclosed by us in such reports is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

**Table of Contents**

**Internal Control over Financial Reporting**

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period to which this report relates that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings.**

From time to time, we could be subject to claims arising in the ordinary course of business or be a defendant in lawsuits. While the outcome of such claims or other proceedings cannot be predicted with certainty, our management expects that any such liabilities, to the extent not provided for by insurance or otherwise, will not have a material adverse effect on our financial condition, results of operations or cash flows.

**Item 1A. Risk Factors.**

There have been no material changes from the risk factors previously disclosed in Part I, Item 1A. Risk Factors, of our Annual Report on Form 10-K for the fiscal year ending December 31, 2011.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

The Exhibits listed in the Exhibit Index immediately preceding such Exhibits are filed with or incorporated by reference in this report.

**Table of Contents**

**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.

**INVIVO THERAPEUTICS HOLDINGS CORP.**

*Date: November 13, 2012*

*By: /s/ Frank M. Reynolds*

*Name: Frank M. Reynolds*

*Title: Chief Executive Officer and Chief Financial Officer  
(Principal Executive, Financial and Accounting Officer)*

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit</b>	
<b>Number</b>	<b>Description</b>
31.1/31.2	Certification by the Principal Executive Officer and Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1/32.2	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Label Linkbase Document
101.PRE*	XBRL Taxonomy Presentation Linkbase Document

\* Pursuant to Rule 406T of Regulation S-T, the interactive files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.