INVIVO THERAPEUTICS HOLDINGS CORP.
Form 10-Q
November 05, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

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x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2014.

or

o 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)

Nevada	**36-4528166**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
One Kendall Square Suite B14402	
Cambridge, MA	**02139**
(Address of principal executive offices)	(Zip code)

(617) 863-5500

(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 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 x 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.

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

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

As of October 31, 2014, 93,547,062 shares of the registrant s common stock, $0.00001 par value, were issued and outstanding.

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INVIVO THERAPEUTICS HOLDINGS CORP.

Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2014

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PART I FINANCIAL INFORMATION

Item 1.Financial Statements.

InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Consolidated Balance Sheets

(In thousands, except share and per-share data)

(Unaudited)

	As of	
	September 30, 2014	**December 31, 2013**
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 17,634	$ 13,980
Restricted cash	371	602
Prepaid expenses and other current assets	342	20
Total current assets	18,347	14,602
Property, equipment and leasehold improvements, net	1,797	2,337
Other assets	141	157
Total assets	$ 20,285	$ 17,096
LIABILITIES AND STOCKHOLDERS EQUITY:		
Current liabilities:		
Accounts payable	$ 711	$ 899
Note payable-current portion	37	74
Capital lease payable		3
Derivative warrant liability	2,716	
Accrued expenses	1,351	1,292
Total current liabilities	4,815	2,268
Loan payable	1,920	1,920
Note payable-less current portion		18
Total liabilities	6,735	4,206
Commitments and contingencies		
Stockholders equity:		
	1	1

Common stock, $0.00001 par value, authorized 200,000,000 shares at September 30, 2014 and December 31, 2013; issued and outstanding 93,547,062 and 78,773,736 shares at September 30, 2014 and December 31, 2013, respectively.				
Additional paid-in capital		105,419		94,798
Deficit accumulated during the development stage		(91,870)		(81,909)
Total stockholders equity		13,550		12,890
Total liabilities and stockholders equity	$	20,285	$	17,096

See notes to the unaudited consolidated financial statements.

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Consolidated Statements of Operations

(In thousands, except share and per-share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		November 28, 2005 (inception) to September 30,
	2014	2013	2014	2013	2014
Operating expenses:					
Research and development	$ 2,385	$ 3,021	$ 8,678	$ 6,825	$ 34,471
General and administrative	1,800	2,386	5,317	6,505	28,444
Total operating expenses	4,185	5,407	13,995	13,330	62,915
Operating loss	(4,185)	(5,407)	(13,995)	(13,330)	(62,915)
Other income (expense):					
Other income					383
Interest income	2	4	4	13	75
Interest expense	(35)	(34)	(102)	(95)	(1,370)
Modification of warrants				(765)	(765)
Derivatives gain (loss)	3,005		4,132	(18,871)	(27,278)
Other income (expense), net	2,972	(30)	4,034	(19,718)	(28,955)
Net loss	$ (1,213)	$ (5,437)	$ (9,961)	$ (33,048)	$ (91,870)
Net loss per share, basic	$ (0.01)	$ (0.07)	$ (0.12)	$ (0.46)	$ (2.09)
Net loss per share, diluted	$ (0.01)	$ (0.07)	$ (0.12)	$ (0.46)	$ (2.09)
Weighted average number of common shares outstanding, basic	101,635,856	78,603,114	81,761,045	72,391,396	44,047,625
Weighted average number of common shares outstanding, diluted	101,635,856	78,603,114	81,761,045	72,391,396	44,047,625

See notes to the unaudited consolidated financial statements.

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended September 30,		Period from November 28, 2005 (inception) to September 30,
	2014	2013	2014
Cash flows from operating activities:			
Net loss	$ (9,961)	$ (33,048)	$ (91,870)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	568	545	1,913
Non-cash derivatives (gain) loss	(4,132)	18,871	27,278
Non-cash interest expense			985
Non-cash loss from modification of warrants		765	765
Common stock issued to 401(k) plan	118	124	443
Common stock issued for services	282		516
Share-based compensation expense	2,278	2,201	8,447
Changes in operating assets and liabilities:			
Restricted cash	230		(372)
Prepaid expenses	(322)	26	(353)
Other assets	3	3	(192)
Accounts payable	(188)	(445)	711
Accrued interest payable	21		6
Accrued expenses	38	242	1,330
Net cash used in operating activities	(11,065)	(10,716)	(50,393)
Cash flows from investing activities:			
Purchases of property and equipment	(14)	(651)	(3,534)
Net cash used in investing activities	(14)	(651)	(3,534)
Cash flows from financing activities:			
Proceeds from issuance of note payable		150	150
Repayment of note payable	(55)		(112)
Proceeds from issuance of convertible notes payable			4,181
Proceeds from convertible bridge notes			500
Principal payments on capital lease obligation	(3)	(25)	(94)
Proceeds from loan payable		342	2,241
Repayment of loan payable net			(321)
Proceeds from issuance of common stock and warrants	14,791	16,408	65,016
Net cash provided by financing activities	14,733	16,875	71,561
Increase in cash and cash equivalents	3,654	5,508	17,634
Cash and cash equivalents at beginning of period	13,980	12,825	

Cash and cash equivalents at end of period	$ 17,634	$ 18,333	$ 17,634

See notes to the unaudited consolidated financial statements.

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Consolidated Statements of Cash Flows (Concluded)

(In thousands)

(Unaudited)

	Nine Months Ended, September 30,		Period from November 28, 2005 (inception) to September 30,
	2014	2013	2014
Supplemental disclosure of cash flow information and non-cash transactions:			
Cash paid for interest	$ 77	$ 91	$ 359
Conversion of convertible notes payable and accrued interest into common stock	$	$	$ 4,672
Conversion of convertible bridge note payable and accrued interest into common stock	$	$	$ 505
Asset acquired through capital lease obligation	$	$	$ 94
Beneficial conversion feature on convertible and bridge notes payable	$	$	$ 134
Fair value of warrants issued with bridge notes payable	$	$	$ 179
Fair value of warrants issued in connection with loan agreement	$	$	$ 42
Fair value of warrants issued in connection with underwriting agreement	$ 6,848	$	$ 6,848
Reclassification of derivative warrant liability to additional paid-in capital	$	$ 33,456	$ 38,104

See notes to the unaudited consolidated financial statements.

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Notes to Consolidated Financial Statements for the Quarter Ended September 30, 2014 (Unaudited)

1. NATURE OF OPERATIONS, BASIS OF PRESENTATION AND RECENT ACCOUNTING PRONOUNCEMENTS

Business

InVivo Therapeutics Holdings Corp. was incorporated on April 2, 2003, and on October 26, 2010, acquired the business of InVivo Therapeutics Corporation, which was incorporated on November 28, 2005, and are continuing the existing business operations of InVivo Therapeutics Corporation as a wholly-owned subsidiary of InVivo Therapeutics Holdings Corp. Unless otherwise noted herein, the Company or InVivo refers to InVivo Therapeutics Holdings Corp. and its wholly owned subsidiary on a consolidated basis. The Company is a pioneering biomaterials and biotechnology company with a focus on treatment of spinal cord injuries. Its proprietary technologies incorporate intellectual property licensed under the Company s exclusive, world-wide license from Children s Medical Center Corporation (CMCC) and the Massachusetts Institute of Technology (MIT) and intellectual property that has been developed internally, including in collaboration with its advisors and partners.

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.

Basis of Presentation

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, 2013 included in the Company s Annual Report on Form 10-K as filed with the United States Securities and Exchange Commission (SEC) on March 17, 2014 and amended on April 29, 2014. 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, 2014 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.

Recently Issued Accounting Pronouncements

In April 2014, the Financial Accounting Standards Board (the FASB) issued Accounting Standards Update (ASU) 2014-08, Presentation of Financial Statements and Property, Plant, and Equipment - Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity. ASU 2014-08 provides new guidance related to the definition of a discontinued operation and requires new disclosures of both discontinued operations and certain other disposals that do not meet the definition of a discontinued operation. This new guidance is effective for annual periods beginning on or after December 15, 2014 and interim periods within those years. Beginning in 2015, the Company will apply the new guidance, as applicable, to future disposals of components or classifications as held for sale.

In June 2014, the FASB issued ASU 2014-10, Development Stage Entities, Topic 915. The ASU 2014-10 removes Topic 915, Development Stage Entities in its entirety from FASB Accounting Standards Codification (ASC). It also eliminates the guidance in ASC 810 on how to assess whether a development stage entity has sufficient equity at risk in the evaluation of whether the development stage entity is a variable interest entity. Additionally, the ASU 2014-10 clarifies that all entities, including entities that have not begun operations, should provide the risk and uncertainty disclosures required in ASC 275. The amendments made by ASU 2014-10 are for annual reporting periods beginning after December 15, 2014, and interim periods therein. Early adoption is permitted. The Company is assessing the impact of ASU 2014-10 on its disclosures.

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2. CASH AND CASH EQUIVALENTS

As of September 30, 2014, the Company held $17,634,000 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. The Company s cash equivalents are held in money market funds. Cash and cash equivalents consisted of the following (in thousands):

	September 30, 2014	December 31, 2013
Cash	$ 336	$ 219
Money market fund	17,298	13,761
Total cash and cash equivalents	$ 17,634	$ 13,980

3. RESTRICTED CASH

Restricted cash for the nine months ended September 30, 2014 was $371,000 and represented $60,000 of security deposits related to the Company s credit card account and a $311,000 cash account securing a standby letter of credit in favor of a landlord (see Note 5).

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.

Assets and liabilities measured at fair value on a recurring basis are summarized below (in thousands):

	At September 30, 2014			
	Level 1	Level 2	Level 3	Fair Value
Liabilities:				
Derivative warrant liability	$	$ 2,716	$	$ 2,716

	At December 31, 2013			
	Level 1	Level 2	Level 3	Fair Value
Liabilities:				
Derivative warrant liability	$	$	$	$

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5. COMMITMENTS AND CONTINGENCIES

Operating Lease Commitment

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, Massachusetts (as subsequently amended, the Cambridge Lease). The term of the Cambridge Lease is for six years and three months, with one five-year extension option. The Cambridge Lease also requires a standby letter of credit in the amount of $311,000 (see Note 3).

The Cambridge Lease contains certain rent escalation clauses. The Company recognizes rent expense on a straight-line basis over the term of the Cambridge Lease and records the difference between the amount charged to expense and the rent paid as a deferred rent liability. As of September 30, 2014, the amount of deferred rent liability is $522,000 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 the Company with the finished space on a turnkey basis, the Company views 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 the Company s 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 Company s consolidated balance sheets 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 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, 2014, such leasehold improvements totaled $390,000.

Pursuant to the terms of the Company s non-cancelable lease agreements in effect at September 30, 2014, the future minimum rent commitments are as follows (in thousands):

Year Ended December 31,		
2014		306
2015		1,243
2016		1,269
2017		1,295
2018		1,049
Total	$	5,162

Total rent expense for the nine months ended September 30, 2014 and 2013, including month-to-month leases, was $861,000 and $838,000, respectively. Total rent expense for the three months ended September 30, 2014 and 2013, including month-to-month leases, was $287,000 and $241,000, respectively

On September 4, 2013, the Company entered into a settlement agreement with the landlord of one of its proprieties, which resulted in the receipt of approximately $286,000 in prepaid rent as consideration for the settlement of litigation. The settlement has been included in deferred rent payable, and the benefit will be amortized through rent expense over the lease term.

Litigation

On July 31, 2014, a putative securities class action lawsuit was filed in the United States District Court for the District of Massachusetts, naming our Company and Mr. Reynolds, as defendants. The lawsuit alleges violations of the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements related to the timing and completion of the clinical study of our Scaffold product. The plaintiff seeks class certification for purchasers of our common stock during the

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period from April 5, 2013 through August 26, 2013 and unspecified damages. The Company intends to vigorously defend the lawsuit.

6. ACCRUED EXPENSES

Accrued expenses consisted of the following (in thousands):

	September 30, 2014	December 31, 2013
Accrued bonus	$ 484	$ 566
Accrued payroll	110	101
Deferred rent payable	522	553
Accrued severance	7	
Accrued vacation	116	23
Other accrued expenses	112	49
Total accrued expenses	$ 1,351	$ 1,292

7. NOTE PAYABLE

In May 2013, the Company entered into a contract for the purchase of an Enterprise Resource Planning (ERP) system for $150,000. The total cost for the ERP system, including interest, was approximately $159,000, with an implicit interest rate of approximately 6%.

Pursuant to the terms of the non-cancelable purchase agreement in effect at September 30, 2014, the future minimum principal payments are as follows (in thousands):

Year Ended December 31,	
2014	18
2015	19
Total	$ 37

In the third quarter of 2013, the Company abandoned the implementation of the ERP system. As such, the ERP system cost of $150,000 was fully expensed in 2013.

8. LOAN PAYABLE

In October 2012, the Company entered into a loan agreement with the Massachusetts Development Finance Agency (MassDev). The loan agreement provided the Company with a $2,000,000 line of credit from the Commonwealth of Massachusetts Emerging Technology fund, with $200,000 designated to be used for working capital purposes and the remainder to be used for the purchase of capital equipment. The annual interest rate is fixed at 6.5% with interest only payments for the first thirty months, commencing on November 1, 2012, and then equal interest and principal payments over the next fifty-four months, with the final maturity on October 5, 2019. Based on the $1,920,000 balance outstanding as of September 30, 2014, equal monthly principal payments of approximately $36,000 will be due commencing on May 1, 2015. Therefore, for the years ending December 31, 2015, 2016, 2017, 2018 and 2019, principal payments of approximately $284,000, $427,000, $427,000, $427,000 and $355,000, respectively, will be due. In September 2012, the Company was assessed a commitment fee totaling $15,000, which was charged to the Company as interest expense. In October 2012, the Company issued MassDev a warrant for the purchase of 36,145 shares of its common stock. The warrant has a seven-year term and is exercisable at $1.66 per share. The fair value of the warrant was determined to be $32,000 and was recorded as a deferred financing cost and is being amortized to interest expense over a seven-year period commencing in October 2012. Amortization of the deferred financing cost for the nine months ended September 30, 2014 was $3,000 and is included in interest expense in the Company s consolidated statements of operations. The equipment line of credit is secured by substantially all the assets of the Company, excluding intellectual property. Interest expense related to this loan for the nine months ended September 30, 2014 and 2013 was $95,000 and $90,000, respectively. Interest expense related to this loan for the three months ended September 30, 2014 and 2013 was $32,000 and $32,000, respectively.

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9. COMMON STOCK

The Company has authorized 200,000,000 shares of common stock, $0.00001 par value per share, of which 93,547,062 shares were issued and outstanding as of September 30, 2014 and 78,773,736 shares were issued and outstanding as of December 31, 2013.

During the nine months ended September 30, 2014, the Company issued an aggregate of 476,330 shares of common stock upon the exercise of stock options and received cash proceeds of approximately $162,000.

During the nine months ended September 30, 2014, the Company issued an aggregate of 39,900 shares of common stock upon the exercise of warrants, including warrants to purchase 62,620 shares of common stock exercised through cashless exercise provisions resulting in the issuance of 27,610 shares of common stock and warrants to purchase 12,290 shares of common stock exercised for cash, providing net cash proceeds of approximately $12,000.

During the nine months ended September 30, 2014, the Company issued an aggregate of 124,624 shares of common stock with a fair value of approximately $118,000 to the Company s 401(k) plan as matching contributions.

During the nine months ended September 30, 2014, the Company issued 108,848 and 22,374 shares of common stock to Michael J. Astrue, Interim Chief Executive Officer, and Gregory D. Perry, Interim Chief Financial Officer, respectively, in lieu of executive cash bonuses. Such shares had an aggregate fair value of approximately $282,000.

On May 9, 2014, the Company closed an underwritten public offering of an aggregate of 14,001,250 shares of common stock and warrants to purchase up to an aggregate of 7,000,625 shares of common stock, at a price to the public of $1.15 per share of common stock and $0.00001 per warrant. The net proceeds to the Company, after deducting underwriting discounts and offering expenses, were approximately $14.6 million. The warrants have a per share exercise price of $1.4375, or 125% of the public offering price of the common stock, are exercisable immediately, and expire on May 9, 2019. The Company intends to use the net proceeds from the offering for general corporate purposes, including for research, development and pre-clinical studies for its product candidates, the completion of its Scaffold pilot study, and for working capital.

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, 2014, there were options to purchase an aggregate of 1,799,030 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 and the Company s shareholders subsequently approved the 2010 Equity Incentive Plan (as subsequently amended, 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, 2014, the number of shares authorized for issuance under the 2010 Plan was 11,000,000 shares. As of September 30, 2014, there were options to purchase an aggregate of 7,102,625 shares of common stock outstanding under the 2010 Plan and 3,585,261 shares available for future grants under the 2010 Plan. Options issued under the 2007 Plan and the 2010 Plan are exercisable for up to 10 years from the date of issuance.

Share-based compensation

For stock options issued and outstanding for the nine months ended September 30, 2014 and 2013, the Company recorded non-cash, stock-based compensation expense of approximately $2,278,000 and $2,201,000, respectively, net of forfeitures. For stock options issued and outstanding for the three months ended September 30, 2014 and 2013, the Company recorded non-cash, stock-based compensation expense of $682,000 and $574,000, 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. 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 2007 and 2010 Plans, all of which qualify as plain vanilla, is based on the average of the contractual term (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 were as follows:

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	September 30, 2014
Risk-free interest rate	1.90%
Expected dividend yield	0.00%
Expected term (in years)	6.08
Expected volatility	120.65%

A summary of option activity as of September 30, 2014 and changes for the period then ended are presented below:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2013	8,055,522	$ 1.55		
Granted	2,975,000	$ 2.16		
Forfeited	(1,652,537)	$ 1.87		
Exercised	(476,330)	$ 0.34		
Outstanding at September 30, 2014	8,901,655	$ 1.76	7.38	$ 728,905
Vested at September 30, 2014	3,720,301	$ 1.21	5.07	$ 728,905

The weighted average grant-date fair value of options granted during the nine months ended September 30, 2014 was $1.91 per share. The total fair value of options that vested for the nine months ended September 30, 2014 was $2,062,804. As of September 30, 2014, there was $6,459,750 of total unrecognized compensation expense related to non-vested share-based option compensation arrangements. The unrecognized compensation expense is estimated to be recognized over a period of 2.86 years at September 30, 2014.

11. WARRANTS

The following table presents information about warrants to purchase common stock issued and outstanding at September 30, 2014:

Year Issued	Classification	Number of Warrants	Exercise Price	Date of Expiration
2010	Equity	1,494,603	$ 1.40	10/26/2017 12/3/2017
2010	Equity	1,318,268	$ 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
2012	Equity	36,145	$ 1.66	10/5/2019
2014	Liability	7,000,625	$ 1.44	5/09/2019
Total		10,208,849		
Weighted average exercise price			$ 1.43	

Weighted average life in years	4.06

12. DERIVATIVE INSTRUMENTS

The warrants issued in connection with the Company s May 2014 public offering (see Note 9) have anti-dilution protection provisions that allow for the reduction in the exercise price of the warrants if the Company subsequently issues equity securities, including common stock or any security convertible or exchangeable for shares of common stock, for no consideration or for consideration less than the exercise price of the warrants. Accordingly, through September 2014, these warrants were accounted for as derivative liabilities. The Company used 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. Changes in fair value of the derivative financial instruments are recognized in the Company s consolidated statement of operations as a derivative gain or loss. The warrant

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derivative gains (losses) are non-cash income (expenses); and for the nine months ended September 30, 2014 and 2013, a gain (loss) of $4,132,000 and $(18,871,000), respectively, were included in other income (expense) in the Company s consolidated statement of operations.

	September 30, 2014
Risk-free interest rate	1.63%
Expected dividend yield	0.00%
Expected term (in years)	4.61
Expected volatility	117.75%

The primary underlying risk exposure pertaining to the warrants is the change in fair value of the underlying Common Stock for each reporting period.

Changes in the derivative warrant liability for the nine months ended September 30 are as follows (in thousands):

	Nine Months Ended September 30,	
	2014	2013
Balance at December 31,	$	$ 14,585
Fair value of warrants issued	6,848	
Reduction in derivative liability due to exercise and modification of warrants		(33,456)
Increase (decrease) in the fair value of warrants	(4,132)	18,871
Balance at September 30,	$ 2,716	$

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 elsewhere in this quarterly report and with our historical consolidated financial statements and the related notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2013 (as amended, the 2013 Annual Report). The management s discussion and analysis contains forward-looking statements within the meaning of the safe harbor provisions under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1034, as amended (the Exchange Act). These statements include statements made regarding our commercialization strategy, future operations, capital requirements and other statements on our business plans and strategy, financial position, and market trends. In some cases, you can identify forward-looking statements by terms such as believe, plan, intend, anticipate, target, estimate, expect and other similar expressions. 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, including factors such as our ability to execute our strategy and business plan; the progress and timing of our development programs and regulatory approval for our products; the risk our research and development efforts do not lead to new products; the timing of commercializing our products; market acceptance of our products; our ability to retain management and other key personnel; and other factors detailed under Risk Factors in Item 1A of our 2013 Annual Report and as updated by our quarterly report on Form 10-Q for the quarter ended March 31, 2014. These forward-looking statements speak only as of the date hereof. We do not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this quarterly report, except as required by law.

The discussion and analysis of our financial condition and results of operations are based on our financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us 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, we evaluate such estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe 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

We are a pioneering biomaterials and biotechnology company with a focus on the treatment of spinal cord injuries. Our proprietary technologies incorporate intellectual property that is licensed under our exclusive, world-wide license from Children s Medical Center

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Corporation (CMCC) and the Massachusetts Institute of Technology (MIT), as well as intellectual property that has been developed internally in collaboration with our advisors and partners. At September 30, 2014, we were considered a development stage enterprise and will continue to be so until we commence commercial operations. A development stage enterprise is one in which planned principal operations have not commenced or, if its operations have commenced, there has been no significant revenue from operations. Development stage companies report cumulative costs from the date of inception of the enterprise.

Our development stage started on November 28, 2005 and continues through September 30, 2014. As of September 30, 2014, we have experienced total net losses since inception of approximately $91,870,000. As a development stage enterprise, we expect to incur substantial operating losses in the future and are therefore dependent upon external financing, such as from equity and debt offerings, to finance our operations. Before we can derive revenue or cash inflows from the commercialization of any of our products, we will need to conduct clinical studies and obtain regulatory approval to commercialize our products.

Overall, we expect our research and development (R&D) expenses to be substantial and to increase for the foreseeable future as we continue the development and clinical investigation of our current and future products. However, expenditures on R&D programs are subject to many uncertainties, including whether we develop our products with a partner or independently, or whether we develop or acquire products and product candidates. At this time, due to the uncertainties and inherent risks involved in our development stage business, we cannot estimate in a meaningful way the duration of, or the costs to complete, our R&D programs or whether, when or to what extent we will generate revenues or cash inflows from the commercialization and sale of any of our products. While we are currently focused on advancing the development of our Neuro-Spinal Scaffold, our future R&D expenses will depend on the determinations we make as to the scientific and clinical prospects of each potential product, as well as our ongoing assessment of the regulatory requirements and each product s commercial potential. In addition, we may make acquisitions of businesses, technologies or intellectual property rights that we believe would be necessary, useful or complementary to our current business. Any investment made in a potential acquisition could affect our results of operations and reduce our limited capital resources, and any issuance of equity securities in connection with a potential acquisition could be substantially dilutive to our stockholders.

There can be no assurance that we will be able to successfully develop or acquire any product, or that we will be able to recover our development or acquisition costs, whether upon commercialization of a developed product or otherwise. We cannot provide assurance that any of our programs under development or any acquired technologies or products will result in products that can be marketed or marketed profitably. If our development-stage programs or any acquired products or technologies do not result in commercially viable products, our results of operations could be materially adversely affected.

Recent Events

Pilot Study Update

Our investigational degradable polymer Neuro-Spinal Scaffold is currently being studied in an early feasibility, five subject pilot study under our approved Investigational Device Exemption application (IDE) for the treatment of complete traumatic acute spinal cord injury. The U.S. Food and Drug Administration (FDA) approved the study which is intended to capture safety and feasibility of the Neuro-Spinal Scaffold for the treatment of complete functional spinal cord injury, as well as to gather preliminary evidence of the clinical effectiveness of the Scaffold.

The pilot study was initially approved for up to six clinical sites across the United States, and as of October 2014, the number of allowable clinical sites was expanded to up to 20. The FDA also approved various changes to the protocol for the study related to the broadening of the study s eligibility criteria. In April 2014, our first approved clinical site, The University of Arizona Medical Center in Tucson, Arizona, opened for enrollment of patients who meet the study criteria. Our second clinical site opened for enrollment at the Carolinas Medical Center in Charlotte, North Carolina in May 2014, and our third clinical site opened for enrollment at the Barrow Neurological Institute in Phoenix, Arizona in June 2014. In October 2014, we announced the opening of our fourth clinical site at the Barnes-Jewish Hospital at Washington University in St. Louis, Missouri.

In October 2014, we also announced that the first participant was enrolled in the pilot study at the Barrow Neurological Institute. Under the conditions of the FDA s approval of our IDE application, our pilot study is staggered such that each patient that meets the study criteria will be followed for three months prior to enrolling the next patient in the clinical study. In addition, following implantation of our Scaffold, we will monitor the patient at intervals of 24 hours, 48 hours, 72 hours and one week after initial implantation; at discharge from the hospital; and at one, three, six and 12 months post-implantation of the Scaffold.

If our pilot clinical study is successful, we then expect to conduct a pivotal study to show safety and probable benefit in order to obtain FDA approval to commence commercialization under a Humanitarian Device Exemption (HDE). However, even if we are able to obtain FDA approval of our Scaffold, because the Scaffold is new, unproven technology, we will have to demonstrate the clinical

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utility of the product and gain acceptance from physicians and obtain third party reimbursement for our product and there can be no assurance that we will be able to do so. For major markets outside the United States, we would be required to seek regulatory approvals in those markets after the clinical studies or trials are conducted in the United States.

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, 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 we believe to be reasonable under the circumstances. Such factors form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from 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 the disclosure provided in our 2013 Annual Report.

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.

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Results of Operations

Comparison of the Three Months Ended September 30, 2014 and 2013 (in thousands)

Research and Development Expenses

Research and development expenses consisted primarily of payments to contract research and development companies and payroll. Research and development expenses for the three months ended September 30, 2014 were $2,385, a decrease of $636 from the quarter ended September 30, 2013. The decline in research and development expenses for the three months ended September 30, 2014 is primarily attributed to costs incurred for the realignment of resources in June 2014 of $789, partly offset by higher costs related to our clinical study of $153.

General and Administrative Expenses

General and administrative expenses consisted primarily of payroll, rent and professional services. General and administrative expenses for the three months ended September 30, 2014 were $1,800, which reflected a reduction of $585 from the same period in the prior year. The reduction in general and administrative expenses for the three months ended September 30, 2014 was related to lower legal expenses of $316, reduced IT costs of $298, a reduction in recruiting fees of $28, and lower travel costs of $142, which was partially offset by an increase in stock compensation expenses of $199.

Other Income and Expense

Other income for the three months ended September 30, 2014 was $2,972, which comprised interest expense of $35, interest income of $2 and a gain in the deferred warrant liability of $3,005. The three months ended September 30, 2014 reflected a benefit of $3,002, as compared to the same period in the prior year, and the increase for the period was primarily related to the change in deferred warrant liability of $3,005. The slight increase in interest expense for the three months ended September 30, 2014 was mainly due to an increase in borrowings under our note payable.

Comparison of the Nine Months Ended September 30, 2014 and 2013 (in thousands)

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2014 were $8,678, an increase of $1,853 as compared to the same period in the prior year. Excluding the $251 adjustment related to the realignment of research and development resources in June 2014 and adjusting for the receipt of $1,100 in proceeds from the settlement of a business interruption claim in the first quarter of 2013, the change for the nine months ended September 30, 2014 as compared to the same period in the prior year was an increase of $502. The increase in research and development expenses for the nine months ended September 30, 2014 was attributed to higher manufacturing and testing costs in the amount of $605 related to preparing the Scaffold for shipment to the clinical sites, higher consulting costs related to the establishment of clinical sites during the period of $776 and an increase in stock compensation expense of $72. The increase was partially offset by a reduction in product development expenses of $670 related to the realignment of resources in June 2014 and lower regulatory costs of $271, which were primarily driven by lower consulting fees.

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2014 were $5,317, a decrease of $1,188 as compared to the same period in the prior year. The decrease in general and administrative expenses for the nine months ended September 30, 2014 is attributed to lower travel costs of $404, decreased legal spending of $306, lower IT costs of $385, a decrease in donations of $95, and a decrease in other expenses totaling $59, which was partly offset by an increase in stock compensation expense of $61.

Other Income and Expense

Other income for the nine months ended September 30, 2014 was $4,034, which was comprised of interest expense of $102, interest income of $4 and a gain in the deferred warrant liability of $4,132. For the nine months ended September 2013, there was a charge of $19,718. The increase is primarily driven by the change in the deferred warrant liability of $23,003 and certain charges associated with warrant modifications of $765. The increase in interest expense for the nine months ended September 30, 2014 was mainly due to an increase in borrowings under our note payable.

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Liquidity and Capital Resources ***(in thousands)***

Since our inception, we have devoted substantially all of our efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. Accordingly, we are considered to be in the development stage.

Since inception, we have experienced negative cash flows from operations. We have financed our operations primarily through sales of equity-related securities. At September 30, 2014, our deficit accumulated during the development stage was $91,870.

At September 30, 2014, we had total current assets of $18,347 and current liabilities of $4,815, resulting in working capital of $13,532. At September 30, 2014, we had total assets of $20,285 and total liabilities of $6,735, resulting in stockholders equity of $13,550.

Net cash used in operating activities for the nine months ended September 30, 2014 was approximately $11,065, as compared to net cash used in operating activities of approximately $10,716 for the nine months ended September 30, 2013. The change in net cash used in operating activities for the nine months ended September 30, 2014 as compared to the same period in the prior year was primarily due to higher operating costs related to the research and development expenses. Significant commitments that will require the use of cash in operating activities in future periods include our obligations under operating leases. Our gross committed lease obligations amount to approximately $5,162. Total commitments due for the remainder of fiscal 2014 under operating leases are approximately $306.

Net cash used in investing activities for the nine months ended September 30, 2014 totaled approximately $14 for purchases of capital equipment, as compared to net cash used in investing activities of $651 for purchases of capital equipment for the nine months ended September 30, 2013.

Net cash provided by financing activities was approximately $14,733 for the nine months ended September 30, 2014 consisting of the proceeds from our May 2014 public offering, as compared to net cash provided by financing activities of approximately $16,875 for the nine months ended September 30, 2013 which is primarily related to proceeds from the exercise of warrants, loans and capital leases net of repayments.

At September 30, 2014, we had cash of approximately $17,634. On May 9, 2014, we completed an underwritten public offering of an aggregate of 14,001,250 shares of common stock and warrants to purchase an aggregate of 7,000,625 shares of common stock, at a price to the public of $1.15 per share of common stock and $0.00001 per warrant. The net proceeds, after deducting underwriting discounts and offering expenses, were approximately $14.6 million. We expect this amount to be sufficient to meet our operating and capital requirements until March 2016, and intend to use the proceeds for general corporate purposes, including for the research, development and pre-clinical studies for our product candidates, the completion of our Scaffold pilot clinical study, and for working capital.

However, we have incurred significant operating losses and negative cash flows since inception. We have not achieved profitability and may not be able to realize sufficient revenue to achieve or sustain profitability in the future. We do not expect to be profitable in the next several years, but rather expect to incur additional operating losses. We have limited liquidity and capital resources and must obtain significant additional capital resources in order to sustain our product development efforts, for acquisition of technologies and intellectual property rights, for

preclinical and clinical testing of our anticipated products, for pursuit of regulatory approvals, for acquisition of capital equipment, laboratory and office facilities, for establishment of production capabilities, and for selling, general and administrative expenses and other working capital requirements. We have, in the past, successfully completed financings, but, due to market conditions and other factors, including our development stage and our ability to continue as a going concern, we may be unable to raise the capital required to execute our business plan in the future or on acceptable terms.

We intend to pursue opportunities to obtain additional financing in the future through equity and/or debt financings. We have filed with the SEC, and the SEC declared effective, a universal shelf registration statement which permits us to issue up to $100 million worth of registered equity securities. Under this effective shelf registration, we have the flexibility to issue registered securities, from time to time, in one or more separate offerings or other transactions with the size, price and terms to be determined at the time of issuance. Registered securities issued using this shelf may be used to raise additional capital to fund our working capital and other corporate needs, for future acquisitions of assets, programs or businesses, and for other corporate purposes.

The source, timing and availability of any future financing will depend principally upon market conditions, interest rates and, more specifically, on our progress in our exploratory, preclinical and future clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or

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eliminate some or all of our research and product development programs, planned clinical studies or trials, and our capital expenditures or to license our potential products or technologies to third parties.

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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to change in interest rates which could affect our operating results, financial position and cash flows. We manage our exposure to these market risks through our regular operating and financing activities. We do not use derivative financial instruments for speculative or trading purposes. For discussion of our market risk exposure, refer to Item 7A., Quantitative and Qualitative Disclosures About Market Risk, in our 2013 Annual Report. There are no material changes in market risk from the disclosure provided in our 2013 Annual Report.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act, as amended) as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and our 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 our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

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.

In November 2013, we filed a lawsuit against Francis Reynolds, our former Chairman, Chief Executive Officer and Chief Financial Officer, in Middlesex Superior Court, Middlesex County, Massachusetts (*InVivo Therapeutics Holdings Corp. v. Reynolds, Civil Action No. 13-5004*). The complaint alleges breaches of fiduciary duties, breach of contract, conversion, misappropriation of corporate assets, unjust enrichment, corporate waste, and seeks money damages and an accounting. The lawsuit involves approximately $500,000 worth of personal and/or exorbitant expenses that we allege Mr. Reynolds inappropriately caused us to pay while he was serving as our Chief Executive Officer, Chief Financial Officer, President and Chairman of our Board of Directors. On December 6, 2013, Mr. Reynolds answered the complaint and filed counterclaims against us and our Board of Directors. The counterclaims allege two counts of breach of contract, two counts of breach of the covenant of good faith and fair-dealing, and tortious interference with a contract, and seek monetary damages and a declaratory judgment. The counterclaims involve Mr. Reynolds s allegations that we and our Board interfered with the performance of his duties under the terms of his employment agreement and that Mr. Reynolds was entitled to additional shares upon the exercise of certain stock options. On January 9, 2014, we, along with the directors named in the counterclaims, filed our answer. The parties are currently conducting pre-trial discovery. No judgments or rulings are pending at this early stage.

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In June 2014, Mr. Reynolds filed a complaint with the Massachusetts Commission Against Discrimination (MCAD) alleging that we discriminated against him on the basis of physical disability in violation of Massachusetts law and the Americans with Disability Act. We filed a written response to the complaint denying the claim. Mr. Reynolds withdrew his MCAD complaint on September 15, 2014.

On July 31, 2014, a putative securities class action lawsuit was filed in the United States District Court for the District of Massachusetts, naming our Company and Mr. Reynolds, as defendants. The lawsuit alleges violations of the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements related to the timing and completion of the clinical study of our Scaffold product. The plaintiff seeks class certification for purchasers of our common stock during the period from April 5, 2013 through August 26, 2013 and unspecified damages. The Company intends to vigorously defend the lawsuit.

In addition to the disclosure above, from time to time, we could also be subject to other 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 in the risk factors previously disclosed in Part I, Item 1A. Risk Factors of our Annual Report on Form 10-K for the fiscal year ended December 31, 2013 as updated by our quarterly report on Form 10-Q for the quarter ended March 31, 2014.

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 quarterly report.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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 5, 2014	By:	/s/ Steven F. McAllister
	Name:	Steven F. McAllister
	Title:	Chief Financial Officer (Principal Financial Officer)

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EXHIBIT INDEX

Exhibit Number	Description
31.1	Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of the Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the 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