

INVIVO THERAPEUTICS HOLDINGS CORP.

Form 10-Q

November 04, 2015

[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, 2015

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: 001-37350

InVivo Therapeutics Holdings Corp.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of
incorporation or organization)

36-4528166

(I.R.S. Employer
Identification Number)

One Kendall Square

Suite B14402

Cambridge, MA

(Address of principal executive offices)

02139

(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 ☒ 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 ☐

Accelerated filer ☒

Non-accelerated filer ☐

(Do not check if a smaller reporting company)

Smaller reporting company ☐

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

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

As of October 29, 2015, 27,357,631 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 Quarter Ended September 30, 2015

TABLE OF CONTENTS

	Page
<u>PART I</u>	3
<u>FINANCIAL INFORMATION</u>	3
<u>1. Financial Statements (Unaudited)</u>	3
<u>Consolidated Balance Sheets as of September 30, 2015 and December 31, 2014</u>	3
<u>Consolidated Statements of Operations for the Three Months and Nine Months Ended September 30, 2015 and 2014</u>	4
<u>Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2015 and 2014</u>	5
<u>Notes to Consolidated Financial Statements</u>	7
<u>2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
<u>3. Quantitative and Qualitative Disclosures about Market Risk</u>	18
<u>4. Controls and Procedures</u>	18
<u>PART II</u>	18
<u>OTHER INFORMATION</u>	18
<u>1. Legal Proceedings</u>	18
<u>1A. Risk Factors</u>	19
<u>2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	19
<u>3. Defaults Upon Senior Securities</u>	19
<u>4. Mine Safety Disclosures</u>	19
<u>5. Other Information</u>	19
<u>6. Exhibits</u>	19

[Table of Contents](#)**PART I FINANCIAL INFORMATION****SPECIAL NOTE**

All share number and share prices presented in this Quarterly Report on Form 10-Q have been adjusted to reflect the 1-for-4 reverse stock split of InVivo Therapeutics Holdings Corp.'s common stock effected on April 8, 2015.

Item 1. Financial Statements.**InVivo Therapeutics Holdings Corp.****Consolidated Balance Sheets**

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

(Unaudited)

	September 30, 2015	As of December 31, 2014
ASSETS:		
Current assets:		
Cash and cash equivalents	\$ 22,146	\$ 13,459
Restricted cash	361	422
Prepaid expenses and other current assets	268	1,072
Total current assets	22,775	14,953
Property, equipment and leasehold improvements, net	1,093	1,605
Other assets	119	135
Total assets	\$ 23,987	\$ 16,693
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	\$ 797	\$ 569
Loan payable-current portion	389	320
Note payable		18
Derivative warrant liability	2,451	7,224
Accrued expenses	1,908	1,044
Total current liabilities	5,545	9,175
Loan payable, net of current portion	1,376	1,600

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

Total liabilities	6,921	10,775
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.00001 par value, authorized 50,000,000 shares; issued and outstanding 27,042,740 and 23,453,000 shares at September 30, 2015 and December 31, 2014, respectively.	1	1
Additional paid-in capital	145,901	106,172
Accumulated deficit	(128,836)	(100,255)
Total stockholders' equity	17,066	5,918
Total liabilities and stockholders' equity	\$ 23,987	\$ 16,693

See notes to the unaudited consolidated financial statements.

Table of Contents**InVivo Therapeutics Holdings Corp.****Consolidated Statements of Operations****(In thousands, except share and per-share data)****(Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	\$ 2,432	\$ 2,385	\$ 7,280	\$ 8,678
General and administrative	3,437	1,800	9,861	5,317
Total operating expenses	5,869	4,185	17,141	13,995
Operating loss	(5,869)	(4,185)	(17,141)	(13,995)
Other income (expense):				
Interest income	2	2	6	4
Interest expense	(32)	(35)	(97)	(102)
Derivatives gain (loss)	3,591	3,005	(11,349)	4,132
Other income (expense), net	3,561	2,972	(11,440)	4,034
Net loss	\$ (2,308)	\$ (1,213)	\$ (28,581)	\$ (9,961)
Net loss per share, basic and diluted	\$ (0.09)	\$ (0.05)	\$ (1.09)	\$ (0.46)
Weighted average number of common shares outstanding, basic and diluted	27,010,444	23,364,731	26,150,525	21,635,774

See notes to the unaudited consolidated financial statements.

Table of Contents
InVivo Therapeutics Holdings Corp.
Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	\$ (28,581)	\$ (9,961)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	527	568
Non-cash derivatives (gain) loss	11,349	(4,132)
Common stock issued to 401(k) plan	157	118
Common stock issued for services		282
Share-based compensation expense	3,614	2,278
Changes in operating assets and liabilities:		
Restricted cash	61	230
Prepaid expenses	804	(322)
Other assets	3	3
Accounts payable	228	(188)
Accrued expenses	865	59
Net cash used in operating activities	(10,973)	(11,065)
Cash flows from investing activities:		
Purchases of property and equipment	(2)	(14)
Net cash used in investing activities	(2)	(14)
Cash flows from financing activities:		
Proceeds from exercise of stock options	1,009	
Repayment of loan payable	(155)	(55)
Proceeds from exercise of warrants	7,788	
Repayment of note payable	(18)	
Principal payments on capital lease obligation		(3)
Proceeds from issuance of common stock and warrants	11,038	14,791
Net cash provided by financing activities	19,662	14,733
Increase (decrease) in cash and cash equivalents	8,687	3,654
Cash and cash equivalents at beginning of period	13,459	13,980
Cash and cash equivalents at end of period	\$ 22,146	\$ 17,634

See notes to the unaudited consolidated financial statements.

Table of Contents

InVivo Therapeutics Holdings Corp.

Consolidated Statements of Cash Flows (Concluded)

(In thousands)

(Unaudited)

	Nine Months Ended, September 30,	
	2015	2014
Supplemental disclosure of cash flow information and non-cash investing and financing transactions:		
Cash paid for interest	\$ 97	\$ 77
Fair value of warrants issued in connection with underwriting agreement	\$	\$ 6,848
Reclassification of derivative warrant liability to additional paid-in capital in connection with exercises	\$ 16,122	\$

See notes to the unaudited consolidated financial statements.

Table of Contents

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements for the Quarter Ended September 30, 2015 (Unaudited)

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

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 continued 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 research and clinical-stage biomaterials and biotechnology company with a focus on the treatment of spinal cord injuries. Its proprietary technologies incorporate intellectual property licensed under the Company's exclusive, world-wide license from the Boston Children's Hospital and the Massachusetts Institute of Technology, as well as intellectual property that has been developed internally 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.

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, 2014 included in the Company's Annual Report on Form 10-K as filed with the United States Securities and Exchange Commission (SEC) on March 11, 2015. 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, 2015 and its results of operations and cash flows for the interim period 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.

Reverse Stock Split

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

On April 8, 2015, the Company effected a reverse stock split of its common stock, par value \$0.00001 per share, at a ratio of 1-for-4. As a result of the reverse stock split, (i) every four shares of the issued and outstanding common stock were automatically converted into one newly issued and outstanding share of common stock, without any change in the par value per share; (ii) the number of shares of common stock into which each outstanding warrant or option to purchase common stock is exercisable was proportionally decreased, and (iii) the number of shares of authorized shares of common stock outstanding was proportionally decreased. Shares of common stock underlying outstanding stock options and other equity instruments convertible into common stock were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities.

Unless otherwise indicated, all of the Company's historical share and per share information related to issued and outstanding common stock and outstanding options and warrants exercisable for common stock in these financial statements have been adjusted, on a retroactive basis, to reflect this 1-for-4 reverse stock split.

Recently Issued Accounting Pronouncements

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements - Going Concern*, on disclosure of uncertainties about an entity's ability to continue as a going concern. This guidance addresses management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosures. The guidance is effective for fiscal years beginning after December 15, 2016 and for interim periods within those fiscal years, with early adoption permitted. The Company does not expect the adoption of this guidance to have

Table of Contents**InVivo Therapeutics Holdings Corp.****Notes to Consolidated Financial Statements for the Quarter Ended September 30, 2015 (Unaudited)****(In thousands, except share and per-share data)**

material impact on our consolidated financial statements.

In April 2015, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2015-03, "Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs". ASU 2015-03 is intended to simplify the presentation of debt issuance costs. These amendments require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this ASU. This new guidance is effective for fiscal years beginning after December 15, 2015 and interim periods within those fiscal years. Early adoption is permitted. The Company is currently in the process of evaluating the impact of the adoption of this ASU on the financial statements.

2. CASH AND CASH EQUIVALENTS

As of September 30, 2015, the Company held \$22,146 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:

	September 30, 2015	December 31, 2014
Cash	\$ (27)	\$ 269
Money market fund	22,173	13,190
Total cash and cash equivalents	\$ 22,146	\$ 13,459

3. RESTRICTED CASH

Restricted cash as of September 30, 2015 was \$361 and represented \$50 of security deposits related to the Company's credit card account and a \$311 cash account securing a standby letter of credit in favor of a landlord (see Note 5).

4. FAIR VALUE OF ASSETS AND LIABILITIES

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

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**InVivo Therapeutics Holdings Corp.****Notes to Consolidated Financial Statements for the Quarter Ended September 30, 2015 (Unaudited)****(In thousands, except share and per-share data)**

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

Description:	At September 30, 2015			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	\$ 11,002	\$	\$	\$ 11,002
Derivative warrant liability	\$	\$ 2,451	\$	\$ 2,451

Description:	At December 31, 2014			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	\$ 11,000	\$	\$	\$ 11,000
Derivative warrant liability	\$	\$ 7,224	\$	\$ 7,224

See footnote 12, derivative instruments, for further information related to the derivative warrant liability.

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 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 (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, 2015, the amount of deferred rent liability is \$417 and is included in accrued expenses.

Pursuant to the terms of the Company's non-cancelable lease agreements in effect at September 30, 2015, the future minimum rent commitments are as follows:

Year Ended December 31,

2015		312
2016		1,263
2017		1,289
2018		1,092
Total	\$	3,956

Total rent expense for the nine months ended September 30, 2015 and 2014, including month-to-month leases, was \$891 and \$861, respectively. Total rent expense for each of the three month periods ended September 30, 2015 and 2014, including month-to-month leases, was \$297 and \$287, respectively.

Table of Contents

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements for the Quarter Ended September 30, 2015 (Unaudited)

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

On September 4, 2013, the Company entered into a settlement agreement with the landlord of the Cambridge Lease, which resulted in the receipt of approximately \$286 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 term of the Cambridge Lease.

Litigation

Lawsuit with Former Employee

In November 2013, the Company filed a lawsuit against Francis Reynolds, its 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 monetary damages and an accounting. The lawsuit involves approximately \$500,000 worth of personal and/or exorbitant expenses that the Company alleges Mr. Reynolds inappropriately caused it to pay while he was serving as the Company's Chief Executive Officer, Chief Financial Officer, President and Chairman of the Board of Directors. On December 6, 2013, Mr. Reynolds answered the complaint, and filed counterclaims against the Company and the 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 the Company and the 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, the Company, along with the directors named in the counterclaims, filed its answer. The parties are currently conducting pre-trial discovery. No judgments or rulings are pending at this stage.

Shareholder Matters and Investigations

On July 31, 2014, a putative securities class action lawsuit was filed in the United States District Court for the District of Massachusetts, naming the Company and Mr. Reynolds, as defendants (the "Securities Class Action"). 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 the Company's Neuro-Spinal Scaffold. The plaintiff seeks class certification for purchasers of the Company's common stock during the period from April 5, 2013 through August 26, 2013 and unspecified damages. On April 3, 2015, the United States District Court for the District of Massachusetts dismissed the plaintiff's claim with prejudice. Plaintiff filed a notice of appeal of this decision on May 4, 2015. A mandatory mediation conference was held on September 10, 2015. Following that conference, on October 5, 2015, plaintiff filed its opening brief with the United States Court of Appeals for the First Circuit. The defendants are scheduled to file their answering brief on November 5, 2015, with any reply brief of the plaintiff due thirty days thereafter.

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

On January 23, 2015, Shawn Luger, a purported shareholder of the Company, sent the Company a letter demanding that the Board take action to remedy purported breaches of fiduciary duties allegedly related to the claimed false and misleading statements that were the subject of the Securities Class Action (the Shareholder Demand). The Board has completed its investigation of the matters raised in the Shareholder Demand and voted unanimously not to pursue any litigation against any current or former director, officer or employee of the Company with respect to the matters set forth in the Shareholder Demand.

On August 14, 2015, Shawn Luger filed a shareholder derivative law suit on behalf of InVivo Therapeutics against certain present and former board members and company executives related to purported breaches of fiduciary duties allegedly related to the claimed false and misleading statements that were the subject of the Securities Class Action. Per the parties stipulated schedule, the Company and the other defendants are to file their motion to dismiss this action by November 23, 2015.

In addition to the derivative law suit, the Company has received investigation subpoenas from the Boston Regional Office of the Securities and Exchange Commission (the SEC) and the Massachusetts Securities Division of the Secretary of the Commonwealth of Massachusetts (the MSD) requesting corporate documents also concerning, among other topics, the allegations raised in the Securities Class Action and the Shareholder Demand. On October 21, 2015, the Company received a letter from the SEC notifying the Company that it has concluded its investigation of the Company and that it does not intend to recommend an enforcement action against the Company. The Company is cooperating with the MSD investigation.

6. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	September 30, 2015	December 31, 2014
Accrued bonus	\$ 847	\$ 360
Accrued legal	133	49
Accrued payroll	148	505
Deferred rent payable	417	72
Accrued vacation	232	58
Other accrued expenses	131	
Total accrued expenses	\$ 1,908	\$ 1,044

Table of Contents

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements for the Quarter Ended September 30, 2015 (Unaudited)

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

7. NOTE PAYABLE

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

Pursuant to the terms of the non-cancelable purchase agreement the total cost of the ERP system was paid in full during the three months ended March 31, 2015. In the third quarter of 2013, the Company abandoned the implementation of the ERP system. As such, the ERP system cost of \$150 was fully expensed in 2013. The Company reserves the right to implement the ERP system at a future date.

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 line of credit from the Massachusetts Emerging Technology Fund, with \$200 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. Equal monthly principal payments of approximately \$41 became due commencing on May 1, 2015. Therefore, for the years ending December 31, 2015, 2016, 2017, 2018 and 2019, principal payments of \$250, \$396, \$423, \$451 and \$400, respectively, will be due. In October 2012, the Company issued MassDev a warrant for the purchase of 9,037 shares of its common stock. The warrant has a seven-year term and is exercisable at \$6.64 per share. The fair value of the warrant was determined to be \$32 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, 2015 was \$3 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, 2015 and 2014 was \$97 and \$95, respectively. Interest expense related to this loan for each of the three month periods ended September 30, 2015 and 2014 was \$32 and \$32, respectively.

9. COMMON STOCK

The Company has authorized 50,000,000 shares of common stock, \$0.00001 par value per share, of which 27,042,740 shares were issued and outstanding as of September 30, 2015 and 23,453,000 shares were issued and outstanding as of December 31, 2014.

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

During the nine months ended September 30, 2015, the Company issued an aggregate of 198,051 shares of common stock upon the exercise of stock options, including stock options to purchase 44,921 shares of common stock exercised through cashless exercise provisions resulting in the issuance of 13,695 shares of common stock and stock options to purchase 184,355 shares of common stock exercised for cash, providing cash proceeds of \$1,009.

During the nine months ended September 30, 2015, the Company issued an aggregate of 1,378,329 shares of common stock upon the exercise of warrants, including warrants to purchase 36,937 shares of common stock exercised through cashless exercise provisions resulting in the issuance of 23,886 shares of common stock and warrants to purchase 1,354,443 shares of common stock exercised for cash, providing net cash proceeds of \$7,788.

During the nine months ended September 30, 2015, the Company issued an aggregate of 11,847 shares of common stock with a fair value of \$157 to the Company's 401(k) plan as matching contributions.

In January 2015, the Company closed a registered direct offering of an aggregate of 2,000,000 shares of common stock, resulting in net proceeds of \$11,038.

As part of the adjustment to reflect the 1-for-4 reverse stock split on April 8, 2015, 1,514 shares were issued to account for the fractional roundup of shareholders.

In July 2015, the Company entered into a Sales Agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen") pursuant to which the Company may issue and sell from time to time shares of Common Stock having aggregate sales proceeds of up to \$50 million through an at the market equity offering program under which Cowen acts as the Company's sales agent. The Company is required to pay Cowen a commission of 3% of the gross proceeds from the sale of shares of Common Stock under the Sales Agreement.

The Company issued no shares of common stock under the Sales Agreement during the three months ended September 30, 2015. Following the end of the third quarter and through the date of the filing, we have raised approximately \$2,355, net, through this facility (See note 13).

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, 2015, there were options to purchase an aggregate of 368,159 shares of common stock outstanding under the 2007 Plan and no shares available for future grants under the 2007 Plan.

Table of Contents

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements for the Quarter Ended September 30, 2015 (Unaudited)

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

On October 26, 2010, the Company's Board of Directors adopted the 2010 Equity Incentive Plan, which was subsequently approved by the Company's shareholders (the 2010 Plan). The 2010 Plan provided 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. The Company's shareholders approved subsequent amendments in 2012 and 2013 to increase the number of shares available for issuance under the 2010 Plan.

In 2015, the Company's Board of Directors adopted the 2015 Equity Incentive Plan, which was subsequently approved by the Company's shareholders on June 16, 2015 (the 2015 Plan, and together with the 2007 Plan and 2010 Plan, the Plans). The 2015 Plan replaced the 2010 Plan, and no further grants will be made under the 2010 Plan. The 2015 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. The total number of shares authorized for issuance under the 2015 Plan is 4,322,355 shares, consisting of 4,000,000 shares plus 322,355 shares that remained available for grant under the 2010 Plan.

As of September 30, 2015, there were outstanding options to purchase an aggregate of 97,650 and 2,080,383 shares of common stock under the 2015 Plan and 2010 Plan, respectively. Options issued under the Plans are exercisable for up to 10 years from the date of issuance.

The Company's Employee Stock Purchase Plan (ESPP) was adopted by the board of directors and approved by the Company's shareholders on June 16, 2015. The plan allows employees to buy company stock twice a year through after-tax payroll deductions at a discount from market. The board of directors initially authorized 187,500 shares issuance under the ESPP. Commencing on the first day of fiscal 2016 and on the first day of each fiscal year thereafter during the term of the ESPP, the number of shares of common stock reserved for issuance shall be increased by the lesser of (i) 1% of our outstanding shares of common stock on such date, (ii) 50,000 shares or (iii) a lesser amount determined by the Board. In no event shall the aggregate number of shares reserved for issuance during the term of the ESPP exceed 1,250,000 shares.

Share-based compensation

For stock options issued and outstanding for the three months ended September 30, 2015 and 2014, the Company recorded non-cash, stock-based compensation expense of approximately \$1,372 and \$682, respectively, net of forfeitures. For the nine months ended September 30, 2015 and 2014, the Company recorded non-cash, stock-based compensation expense of approximately \$3,614 and \$2,278, 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 Plans, all of which qualify as plain vanilla, is based on the average of the contractual term (10 years) and the vesting period (generally,

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

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:

Table of Contents**InVivo Therapeutics Holdings Corp.****Notes to Consolidated Financial Statements for the Quarter Ended September 30, 2015 (Unaudited)****(In thousands, except share and per-share data)**

	September 30, 2015
Risk-free interest rate	1.70%
Expected dividend yield	0.00%
Expected term (in years)	5.91
Expected volatility	118.87%

A summary of option activity as of September 30, 2015 and changes for the period then ended are presented below (in thousands, except per share data):

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2014	2,606,737	\$ 6.58		
Granted	243,899	\$ 13.38		
Forfeited	(75,168)	\$ 9.13		
Exercised	(229,276)	\$ 6.19		
Outstanding at September 30, 2015	2,546,192	\$ 7.17	7.426	\$ 6,032
Vested at September 30, 2015	1,298,027	\$ 6.33	6.247	\$ 3,935

The weighted average grant-date fair value of options granted during the nine months ended September 30, 2015 was \$11.29 per share. The total fair value of options that vested for the nine months ended September 30, 2015 was approximately \$4,151. As of September 30, 2015, there was \$5,365 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 2.48 years at September 30, 2015.

11. WARRANTS

The following table presents information about warrants to purchase common stock issued and outstanding at September 30, 2015:

Year Issued	Classification	Number of Warrants	Exercise Price	Date of Expiration
--------------------	-----------------------	-------------------------------	-----------------------	---------------------------

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

2010	Equity	364,752	\$	5.60	10/26/2017	12/3/2017
2010	Equity	322,543	\$	4.00	8/30/2017	12/3/2017
2011	Equity	4,017	\$	5.60	6/17/2018	
2011	Equity	85,785	\$	12.24	12/21/2016	
2012	Equity	6,054	\$	6.64	10/5/2019	
2014	Liability	395,716	\$	5.75	5/9/2019	
Total		1,178,867				
Weighted average exercise price				\$	5.70	
Weighted average life in years					2.54	

Table of Contents**InVivo Therapeutics Holdings Corp.****Notes to Consolidated Financial Statements for the Quarter Ended September 30, 2015 (Unaudited)****(In thousands, except share and per-share data)****12. DERIVATIVE INSTRUMENTS**

The warrants issued in connection with the Company's May 2014 public offering 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, these warrants are accounted for as derivative liabilities. The Company used the Binomial Lattice 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 derivative gains (losses) are non-cash income (expenses); and for the nine months ended September 30, 2015 and 2014 a gain (loss) of \$(11,349) and \$4,132, respectively, were included in other income (expense) in the Company's consolidated statement of operations.

	September 30, 2015
Risk-free interest rate	0.33%
Expected dividend yield	0.00%
Expected term (in years)	3.61
Expected volatility	95.05%

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, 2015	2014
Balance at December 31,	\$ 7,224	\$ 6,848
Fair value of warrants issued		6,848
Reduction in derivative liability due to exercise of warrants	(16,122)	
Increase (decrease) in the fair value of warrants	11,349	(4,132)
Balance at September 30,	\$ 2,451	\$ 2,716

13. SUBSEQUENT EVENTS

In July 2015, the Company entered into a Sales Agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen") pursuant to which the Company may issue and sell from time to time shares of Common Stock having aggregate sales proceeds of up to \$50 million through an at the market equity offering program under which Cowen acts as the Company's sales agent. The Company is required to pay Cowen a commission of 3% of the gross proceeds from the sale of shares of Common Stock under the Sales Agreement. Following the end of the third quarter and through the date of the filing, the Company has raised approximately \$2,355 net, pursuant to the Sales Agreement.

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, 2014 (the "2014 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 1934, as amended (the "Exchange Act"). These statements include statements made regarding our clinical plans, 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

Table of Contents

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 2014 Annual Report. 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 research and clinical-stage biomaterials and biotechnology company with a focus on the treatment of spinal cord injuries. Our proprietary technologies incorporate intellectual property licensed under an exclusive, world-wide license from Boston Children's Hospital and the Massachusetts Institute of Technology, and intellectual property that has been developed internally, including in collaboration with our advisors and partners. We intend to leverage our platform technology to develop our novel Neuro-Spinal Scaffold, an investigational bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord contusion and is intended to treat acute spinal cord injury, or SCI. We believe our Neuro-Spinal Scaffold will be the foundation of effective therapy for both acute and chronic SCI, and we are continually evaluating other technologies and therapeutics that may be complementary and that offer the potential to bring us closer to our goal of redefining the life of the SCI patient.

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 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 product candidate, 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.

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

We were incorporated on April 2, 2003, under the name of Design Source, Inc. On October 26, 2010, we acquired the business of InVivo Therapeutics Corporation, which was founded in 2005, and continued the existing business operations of InVivo Therapeutics Corporation as our wholly-owned subsidiary. As a result of the merger and related transactions, InVivo Therapeutics Corporation was considered the accounting acquirer and therefore the historical financial results of InVivo Therapeutics Corporation are considered the financial results of the Company on a historical and going-forward basis.

Recent Events

Pilot Study Update

Our investigational degradable polymer Neuro-Spinal Scaffold is currently being studied in an early feasibility 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 the 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 Neuro-Spinal Scaffold.

The pilot study was initially approved for five subjects in 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. We currently have 14 clinical sites open. In October 2015, the FDA approved an expansion of the study to permit enrollment of up to 10 subjects.

In October 2014, we announced that the first subject was enrolled in the pilot study at the Barrow Neurological Institute in Phoenix, Arizona. Under the conditions of the FDA's approval of our IDE application, our pilot study was initially staggered such that each patient that met the eligibility criteria would be followed for three months prior to enrolling the next patient in the study. In December 2014, barring significant safety issues, the FDA approved an expedited enrollment plan. In January 2015, about three months after the first subject was enrolled, we opened enrollment and our second subject was subsequently enrolled at the Carolinas Medical Center in Charlotte, North Carolina. In March 2015, we announced the reopening of subject enrollment for the study and in June 2015, we enrolled a third subject, who was also treated at the Carolinas Medical Center. In August 2015, we enrolled a fourth subject at the UC-Davis Medical Center in Sacramento, California, and in September 2015, the fifth subject in the pilot study was enrolled at the Keck Hospital at the University of Southern California in Los Angeles, California.

We are currently discussing plans with the FDA for the pivotal probable benefit study which may include data from the patients enrolled in the pilot study. We have fostered a collaborative relationship with the FDA, and we are optimistic that we will finalize the pivotal probable benefit study design in the coming months. Assuming that we receive FDA approval, we currently expect the pivotal study will begin in 2016, with estimated completion in 2017, which depending upon the results of the study could enable us to obtain FDA approval to commence commercialization under a HDE. However, even if we are able to obtain FDA approval of our Neuro-Spinal Scaffold, because the Neuro-Spinal Scaffold is new, unproven technology, we will have to demonstrate the clinical 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.

Table of Contents

Reverse Stock Split and Uplisting to Nasdaq

On April 8, 2015, we effected a reverse stock split of our common stock at a ratio of 1-for-4. As a result of the reverse stock split, every four shares of our issued and outstanding common stock were automatically converted into one newly issued and outstanding share of common stock, without any change in the par value per share. Unless otherwise indicated, all of information in this report related to our issued and outstanding common stock and outstanding options and warrants exercisable for common stock have been adjusted, on a retroactive basis, to reflect this 1-for-4 reverse stock split.

Our common stock began trading on The Nasdaq Capital Market under the symbol **NVIV** on April 17, 2015. On August 24, 2015, the listing of our common stock was transferred to the Nasdaq Global Market under the same symbol.

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 2014 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.

Table of Contents

Results of Operations (In Thousands)

Comparison of the Three Months Ended September 30, 2015 and 2014

Research and Development Expenses

Research and development expenses consisted primarily of payments to contract research organizations and payroll. Research and development expenses for the three months ended September 30, 2015 were \$2,432, a increase of \$47 when compared to the three months ended September 30, 2014. The increase in research and development expenses for the three months ended September 30, 2015 is primarily attributed to higher clinical trial costs of \$220 and other spending of \$79. Partly offsetting these increases are lower consulting costs of \$126, lower testing and supplies costs of \$76, lower legal costs related to patents and trademarks of \$50.

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, 2015 were \$3,437, which reflected an increase of \$1,637 when compared to the three months ended September 30, 2014. The increase in general and administrative expenses for the three months ended September 30, 2015 was attributed to higher legal expenses of \$441, higher share-based compensation expense of \$708, higher consulting fees of \$107, an increase in investor relations expenditures of \$61, an increase in Board fees related to two additional directors of \$30, higher salary and bonus expense of \$106 and increased other expenses of \$184.

Other Income and Expense

Other expense for the three months ended September 30, 2015 was \$3,561, which was comprised of interest expense of \$32, interest income of \$2 and a derivative gain of \$3,591. The three months ended September 30, 2015 reflected an increase in expense of \$589 when compared to the three months ended September 30, 2014. The increase in other expense for the three months ended September 30, 2015 was primarily related to the change in deferred warrant liability of \$586.

Comparison of the Nine Months Ended September 30, 2015 and 2014

Research and Development Expenses

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

Research and development expenses consisted primarily of payments to contract research organizations and payroll. Research and development expenses for the nine months ended September 30, 2015 were \$7,280, a decrease of \$1,398 when compared to the nine months ended September 30, 2014. The decline in research and development expenses for the nine months ended September 30, 2015 is primarily attributed to lower salaries and associated benefits costs of \$624 related to the reduction in force during the second quarter of 2014, lower testing and supplies costs of \$694, a reduction in consulting fees of \$618 and lower share-based compensation expenses of \$151. These reductions were partly offset by an increase in clinical trial costs of \$432, recruiting costs of \$69 and other various expenses of \$188.

General and Administrative Expenses

General and administrative expenses consisted primarily of payroll, rent and professional services. General and administrative expenses for the nine months ended September 30, 2015 were \$9,861, which reflected an increase of \$4,544 when compared to the nine months ended September 30, 2014. The increase in general and administrative expenses for the nine months ended September 30, 2015 was attributed to higher legal expenses of \$1,867, higher share-based compensation expense of \$1,486, NASDAQ related fees of \$106, an increase in investor relations expenditures of \$311, higher consulting fees of \$280, an increase in board fees of \$74 and other expenses of \$420.

Other Income and Expense

Other expense for the nine months ended September 30, 2015 was \$11,440, which was comprised of interest expense of \$97, interest income of \$6 and a derivative loss of \$11,349. The nine months ended September 30, 2015 reflected a decrease in expense of \$15,474 when compared to the nine months ended September 30, 2014. The decrease in other expense for the nine months ended September 30, 2015 was primarily related to the change in derivative warrant liability of \$15,481.

Liquidity and Capital Resources

Since 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. At September 30, 2015, we had total assets of \$23,987 and total liabilities of \$6,921, resulting in stockholders' equity of \$17,066 and a net loss of \$28,582.

We have historically financed our operations primarily through the sale of equity-related securities. In January 2015, we closed a registered direct offering of an aggregate of 2,000,000 shares of our common stock, resulting in net proceeds of approximately \$11,038. We believe our current cash and cash equivalents are adequate to fund our operations into the fourth quarter of 2016. At September 30, 2015, we had cash of approximately \$22,146.

Net cash used in operating activities for the nine months ended September 30, 2015 was approximately \$10,973, as compared to net cash used in operating activities of approximately \$11,065 for the nine months ended September 30, 2014. The change in net cash used in operating activities for the nine months ended September 30, 2015 as compared to the same period in the prior year was primarily due to lower operating costs incurred related to prepaid expenses and accounts payable balances. We also have significant commitments that will require the use of cash in operating activities in future periods, including our obligations under current operating leases. Our committed lease obligations amount to approximately \$3,956. Total commitments due for the remainder of fiscal 2015 under operating leases are approximately \$312.

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

Net cash used in investing activities for the nine months ended September 30, 2015 was \$2 for purchases of capital equipment. This compares favorable to the investing activity for the nine months ended September 30, 2014 of \$14.

Net cash provided by financing activities was approximately \$19,662 for the nine months ended September 30, 2015 consisting of the proceeds from our January 2015 offering and the exercise of warrants and stock options as compared to net cash provided by financing activities of approximately \$14,733 for the nine months ended September 30, 2014, which was primarily related to proceeds from the May 2014 offering.

In July 2015, the Company entered into a Sales Agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen") pursuant to which the Company may issue and sell from time to time shares of Common Stock having aggregate sales proceeds of up to \$50 million through an at the market equity offering program under which Cowen acts as the Company's sales agent. The Company is required to pay Cowen a commission of 3% of the gross proceeds from the sale of shares of Common Stock under the Sales Agreement. Following the end of the third quarter and through the date of the filing, we have raised approximately \$2,355, net, through this facility.

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 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.

Table of Contents

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, of which we utilized \$12 million in our January 2015 offering and may use up to \$50 million under the Sales Agreement. 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.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements 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 2014 Annual Report. There are no material changes in market risk from the disclosure provided in our 2014 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 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 (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) 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

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

There have been no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. Legal Proceedings.

Lawsuit with Former Employee

In November 2013, the Company filed a lawsuit against Francis Reynolds, its 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 monetary damages and an accounting. The lawsuit involves approximately \$500,000 worth of personal and/or exorbitant expenses that the Company alleges Mr. Reynolds inappropriately caused it to pay while he was serving as the Company's Chief Executive Officer, Chief Financial Officer, President and Chairman of the Board of Directors. On December 6, 2013, Mr. Reynolds answered the complaint, and filed counterclaims against the Company and the 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 the Company and the 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, the Company, along with the directors named in the counterclaims, filed its answer. The parties are currently conducting pre-trial discovery. No judgments or rulings are pending at this stage.

Shareholder Matters and Investigations

On July 31, 2014, a putative securities class action lawsuit was filed in the United States District Court for the District of Massachusetts, naming the Company and Mr. Reynolds, as defendants (the "Securities Class Action"). 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 the Company's Neuro-Spinal Scaffold. The plaintiff seeks class certification for purchasers of the Company's common stock during the period from April 5, 2013 through August 26, 2013 and unspecified damages. On April 3, 2015, the United States District Court for the District of Massachusetts dismissed the plaintiff's claim with prejudice. Plaintiff filed a notice of appeal of this decision on May 4, 2015. A mandatory mediation conference was held on September 10, 2015. Following that conference, on October 5, 2015, plaintiff filed its opening brief with the United States Court of Appeals for the First Circuit. The defendants are scheduled to file their answering brief on November 5, 2015, with any reply brief of the plaintiff due thirty days thereafter.

On January 23, 2015, Shawn Luger, a purported shareholder of the Company, sent the Company a letter demanding that the Board take action to remedy purported breaches of fiduciary duties allegedly related to the claimed false and misleading statements that were the subject of the Securities Class Action (the "Shareholder Demand"). The Board has completed its investigation of the matters raised in the Shareholder Demand and voted unanimously not to pursue any litigation against any current or former director, officer or employee of the Company with respect to the matters set forth in the Shareholder Demand.

On August 14, 2015, Shawn Luger filed a shareholder derivative law suit on behalf of InVivo Therapeutics against certain present and former board members and company executives related to purported breaches of fiduciary duties allegedly related to the claimed false and misleading

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

statements that were the subject of the Securities Class Action. Per the parties' stipulated schedule, the Company and the other defendants are to file their motion to dismiss this action by November 23, 2015.

In addition to the derivative law suit, the Company has received investigation subpoenas from the Boston Regional Office of the Securities and Exchange Commission (the "SEC") and the Massachusetts Securities Division of the Secretary of the Commonwealth of Massachusetts (the "MSD") requesting corporate documents also concerning, among other topics, the allegations raised Securities Class Action and the Shareholder Demand. On October 21, 2015, the Company received a letter from the SEC notifying the Company that it has concluded its investigation of the Company and that it does not intend to recommend an enforcement action against the Company. The Company is cooperating with the MSD investigation.

Table of Contents

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 2014 Annual Report.

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.

[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 5, 2015

By:	/s/ Steven F. McAllister
Name:	Steven F. McAllister
Title:	Chief Financial Officer (Principal Financial Officer)

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description
1.1	Sales Agreement, dated as of July 29, 2015, between InVivo Therapeutics Holdings Corp. and Cowen and Company, LLC (incorporated by reference from Exhibit 1.1 to the Registrants Current Report on Form 8-K as filed with the SEC on July 29, 2015)
10.1	Letter Agreement regarding Amendments to Employment Agreement, dated as of July 21, 2015, by and between Mark D. Perrin and InVivo Therapeutics Holding Corp.
10.2	Letter Agreement regarding Amendments to Employment Agreement, dated as of July 21, 2015, by and between Steven F. McAllister and InVivo Therapeutics Holdings Corp.
10.3	Employment Agreement, dated July 21, 2015, by and between Thomas R. Ulich, M.D and InVivo Therapeutics Holdings Corp.
10.4	Employment Agreement, dated August 3, 2015, by and between Tamara L. Joseph and InVivo Therapeutics Holdings Corp.
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