

INVIVO THERAPEUTICS HOLDINGS CORP.

Form 10-Q

August 04, 2016

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

Washington, DC 20549

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**FORM 10-Q**

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

**For the quarterly period ended June 30, 2016**

or

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

**For the transition period from                      to                      .**

**Commission File Number: 001-37350**

## InVivo Therapeutics Holdings Corp.

(Exact name of registrant as specified in its charter)

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**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)

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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

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As of July 28, 2016, 31,927,089 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 June 30, 2016**

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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)

|   | June 30,<br>2016 | As of | December 31,<br>2015 |
|---|------------------|-------|----------------------|
| <b>ASSETS:</b>                                      |                  |       |                      |
| Current assets:                                     |                  |       |                      |
| Cash and cash equivalents                           | \$ 41,629        | \$    | 20,194               |
| Restricted cash                                     | 361              |       | 361                  |
| Prepaid expenses and other current assets           | 682              |       | 184                  |
| Total current assets                                | 42,672           |       | 20,739               |
| Property, equipment and leasehold improvements, net | 736              |       | 938                  |
| Other assets  | 102              |       | 115                  |
| Total assets  | \$ 43,510        | \$    | 21,792               |
| <b>LIABILITIES AND STOCKHOLDERS EQUITY:</b>         |                  |       |                      |
| Current liabilities:                                |                  |       |                      |
| Accounts payable                                    | \$ 559           | \$    | 521                  |
| Loan payable, current portion                       | 409              |       | 395                  |
| Derivative warrant liability                        | 2,359            |       | 1,907                |
| Deferred rent, current portion                      | 128              |       | 115                  |
| Accrued expenses                                    | 1,169            |       | 374                  |
| Total current liabilities                           | 4,624            |       | 3,312                |
| Loan payable, net of current portion                | 1,067            |       | 1,275                |

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|  |           |           |
|--|-----------|-----------|
| Deferred rent, net of current portion  | 208       | 276       |
| Total liabilities  | 5,899     | 4,863     |
| Commitments and contingencies  |           |           |
| Stockholders' equity:  |           |           |
| Common stock, \$0.00001 par value, authorized 100,000,000 shares; issued and outstanding 31,917,308 at June 30, 2016, and authorized 50,000,000 shares; issued and outstanding 27,555,948 shares at December 31, 2015. | 1         | 1         |
| Additional paid-in capital   | 182,986   | 150,497   |
| Accumulated deficit  | (145,376) | (133,569) |
| Total stockholders' equity   | 37,611    | 16,929    |
| Total liabilities and stockholders' equity   | \$ 43,510 | \$ 21,792 |

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)**

|  | <b>Three Months Ended<br/>June 30,</b> |             | <b>Six Months Ended<br/>June 30,</b> |             |
|--|--|-------------|--------------------------------------|-------------|
|  | <b>2016</b>                            | <b>2015</b> | <b>2016</b>                          | <b>2015</b> |
| Operating expenses:  |  |             |                                      |             |
| Research and development   | \$ 2,795                               | \$ 2,546    | \$ 5,364                             | \$ 4,848    |
| General and administrative   | 2,991                                  | 3,214       | 5,990                                | 6,422       |
| Total operating expenses   | 5,786                                  | 5,760       | 11,354                               | 11,270      |
| Operating loss   | (5,786)                                | (5,760)     | (11,354)                             | (11,270)    |
| Other income (expense):  |  |             |                                      |             |
| Interest income  | 36                                     | 2           | 91                                   | 3           |
| Interest expense   | (29)                                   | (32)        | (92)                                 | (66)        |
| Derivatives gain (loss)  | 595                                    | (4,653)     | (452)                                | (14,940)    |
| Other income (expense), net  | 602                                    | (4,683)     | (453)                                | (15,003)    |
| Net loss   | \$ (5,184)                             | \$ (10,443) | \$ (11,807)                          | \$ (26,273) |
| Net loss per share, basic and diluted                                      | \$ (0.16)                              | \$ (0.39)   | \$ (0.39)                            | \$ (1.02)   |
| Weighted average number of common shares<br>outstanding, basic and diluted | 31,907,747                             | 26,508,170  | 30,039,677                           | 25,713,438  |

See notes to the unaudited consolidated financial statements.

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

|  | <b>Six Months Ended<br/>June 30,</b> |             |
|--|--------------------------------------|-------------|
|  | <b>2016</b>                          | <b>2015</b> |
| <b>Cash flows from operating activities:</b>                                       |                                      |             |
| Net loss   | \$ (11,807)                          | \$ (26,273) |
| <b>Adjustments to reconcile net loss to net cash used in operating activities:</b> |                                      |             |
| Depreciation and amortization  | 284                                  | 352         |
| Non-cash derivatives loss  | 452                                  | 14,940      |
| Common stock issued to 401(k) plan   | 109                                  | 105         |
| Share-based compensation expense   | 2,396                                | 2,241       |
| <b>Changes in operating assets and liabilities:</b>                                |                                      |             |
| Restricted cash  |                                      | 61          |
| Prepaid expenses   | (498)                                | 675         |
| Other assets   | 4                                    | 3           |
| Accounts payable   | 38                                   | 384         |
| Accrued expenses   | 740                                  | 365         |
| Net cash used in operating activities  | (8,282)                              | (7,147)     |
| <b>Cash flows from investing activities:</b>                                       |                                      |             |
| Purchases of property and equipment  | (73)                                 |             |
| Net cash used in investing activities  | (73)                                 |             |
| <b>Cash flows from financing activities:</b>                                       |                                      |             |
| Proceeds from exercise of stock options  | 36                                   | 978         |
| Proceeds from issuance of stock under ESPP   | 43                                   |             |
| Repayment of loan payable  | (194)                                | (61)        |
| Repayment of note payable  |                                      | (18)        |
| Proceeds from exercise of warrants   |                                      | 6,865       |
| Proceeds from issuance of common stock and warrants                                | 29,905                               | 11,038      |
| Net cash provided by financing activities  | 29,790                               | 18,802      |
| Increase in cash and cash equivalents  | 21,435                               | 11,655      |
| Cash and cash equivalents at beginning of period                                   | 20,194                               | 13,459      |
| Cash and cash equivalents at end of period   | \$ 41,629                            | \$ 25,114   |

See notes to the unaudited consolidated financial statements.



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**InVivo Therapeutics Holdings Corp.**

**Consolidated Statements of Cash Flows (Continued)**

**(In thousands)**

**(Unaudited)**

|  | <b>Six Months Ended,<br/>June 30,</b> |             |
|--|---------------------------------------|-------------|
|  | <b>2016</b>                           | <b>2015</b> |
| <b>Supplemental disclosure of cash flow information and non-cash transactions:</b> |                                       |             |
| Cash paid for interest   | \$ 54                                 | \$ 64       |
| Exercise of equity-classified warrants to common stock                             | \$ 62                                 | \$ 140      |
| Reclassification of derivative warrant liability to additional paid-in capital     | \$                                    | \$ 14,442   |

See notes to the unaudited consolidated financial statements.

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**InVivo Therapeutics Holdings Corp.**

**Notes to Consolidated Financial Statements for the Quarter Ended June 30, 2016 (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 is 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 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 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.

***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, 2015 included in the Company's Annual Report on Form 10-K as filed with the United States Securities and Exchange Commission (SEC) on March 4, 2016. 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 June 30, 2016 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***

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 Company's issued and outstanding common stock were automatically converted into one newly issued and outstanding share of the Company's 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 authorized shares of common stock was proportionally decreased. Shares of common stock underlying outstanding stock

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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.

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 Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update ( ASU ) 2014-15, *Presentation of Financial Statements - Going Concern* (Subtopic 205-40), 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 ending after December 15, 2016 and for annual and interim periods thereafter, with early adoption permitted. The Company is currently in the process of evaluating the impact of the adoption of this ASU on the financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (Topic 842). The guidance in this ASU supersedes the leasing guidance in Topic 840, *Leases*. Under the new guidance, lessees are required to recognize lease assets and lease liabilities on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for annual

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reporting periods beginning after December 15, 2019. The Company is currently evaluating the impact of the adoption of this ASU on the financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation - Stock Compensation* ( ASU 2016-09 ) to require changes to several areas of employee share-based payment accounting in an effort to simplify share-based reporting. The update revises requirements in the following areas: minimum statutory withholding, accounting for income taxes, forfeitures, and intrinsic value accounting for private entities. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2017. The Company is currently evaluating the impact of the adoption of this ASU on the financial statements.

## 2. CASH AND CASH EQUIVALENTS

As of June 30, 2016, the Company held \$41,629 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):

|                                 | June 30,<br>2016 |    | December 31,<br>2015 |
|---------------------------------|------------------|----|----------------------|
| Cash                            | \$ 32            | \$ | 116                  |
| Money market fund               | 41,597           |    | 20,078               |
| Total cash and cash equivalents | \$ 41,629        | \$ | 20,194               |

## 3. RESTRICTED CASH

Restricted cash as of June 30, 2016 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

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.

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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 (see Notes 10 and 11).

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

|                              | At June 30, 2016 |          |         | Fair Value |
|------------------------------|------------------|----------|---------|------------|
|                              | Level 1          | Level 2  | Level 3 |            |
| Cash equivalents             | \$ 41,597        | \$       | \$      | \$ 41,597  |
| Derivative warrant liability | \$               | \$ 2,359 | \$      | \$ 2,359   |

|                              | At December 31, 2015 |          |         | Fair Value |
|------------------------------|----------------------|----------|---------|------------|
|                              | Level 1              | Level 2  | Level 3 |            |
| Cash equivalents             | \$ 20,078            | \$       | \$      | \$ 20,078  |
| Derivative warrant liability | \$                   | \$ 1,907 | \$      | \$ 1,907   |

Table of Contents**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 (the Facility) in Cambridge, Massachusetts (the Cambridge Lease). The term of the Cambridge Lease ends in October 2018 and includes 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 June 30, 2016, the amount of deferred rent liability was \$336.

Pursuant to the terms of the Cambridge Lease, which was non-cancelable and in effect at June 30, 2016, the Company's future minimum rent commitments are as follows (in thousands):

| <b>Year Ended December 31,</b> |    |       |
|--------------------------------|----|-------|
| 2016                           |    | 633   |
| 2017                           |    | 1,289 |
| 2018                           |    | 1,089 |
| Total                          | \$ | 3,011 |

Total rent expense for the three months ended June 30, 2016 and 2015 was \$210 and \$287, respectively. Total rent expense for the six months ended June 30, 2016 and 2015 was \$497 and \$549, respectively.

On March 31, 2016, the Company entered into a short-term sublease with CRISPR Therapeutics, as subtenant, to sub-lease 5,233 square feet of its Facility (the Sublease). The term of the Sublease is from April 1, 2016 through January 31, 2017. At the conclusion of the original Sublease term, the Sublease will move to a month-to-month arrangement with either party having the right to cancel upon 30 days notice. The Company has received \$77 through June 30, 2016 in connection with the Sublease, which was recorded as an offset to rent expense. The Company expects to receive non-cancelable rental income of \$153 in 2016 and \$26 in 2017, which will be recorded as an offset to rent expense.

*Litigation**Lawsuits 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, and corporate waste, and seeks monetary damages and an accounting. The lawsuit involves approximately \$500 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 related to Mr. Reynolds's allegations that the Company and the Board of Directors 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 that he did not receive. On January 9, 2014, the Company, along with the directors named in the counterclaims, filed its answer. No judgments or rulings are pending at this stage.

On July 22, 2016, Mr. Reynolds filed a lawsuit against the Company, certain present and former members of the Company's Board of Directors and an employee of the Company in Hillsborough County Superior Court, Southern District, Hillsborough County, New Hampshire (Reynolds v. InVivo Therapeutics Holdings Corp, et al.) alleging defamation, conspiracy and tortious interference, and seeking monetary damages.

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*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* implant. The plaintiff sought 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.

On May 4, 2015, the plaintiff filed a notice of appeal of this decision. A mandatory mediation conference was held on September 10, 2015. Following that conference, on October 5, 2015, the plaintiff/appellant filed his opening brief with the United States Court of Appeals for the First Circuit. The Company and the individual defendants/appellees filed their answering brief on November 5, 2015, and the plaintiff/appellant filed his reply brief on December 10, 2015. The Court of Appeals heard oral arguments on April 6, 2016.

On January 23, 2015, Shawn Luger, a purported shareholder of the Company, sent the Company a letter (the Shareholder Demand) demanding that the Board of Directors take action to remedy purported breaches of fiduciary duties allegedly related to the claimed false and misleading statements that are the subject of the Securities Class Action. The Board of Directors 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, Mr. Luger filed a shareholder derivative lawsuit in the Superior Court of Suffolk County for the Commonwealth of Massachusetts on behalf of the Company against certain present and former board members and company executives alleging the same breaches of fiduciary duties purportedly set forth in the Shareholder Demand. On February 5, 2016, the Superior Court of Suffolk County dismissed the plaintiff's claims with prejudice. On March 4, 2016, the plaintiff filed a notice of appeal of this decision. On June 15, 2016, plaintiff/appellant filed his opening brief with the Appeals Court of the Commonwealth of Massachusetts. The Company and the individual defendants/appellees filed their answering brief on July 15, 2016. Plaintiff/appellant's reply brief is due on July 29, 2016.

In addition to the derivative lawsuit and the appeal of the Securities Class Action, the Company received investigation subpoenas from the Boston Regional Office of the SEC and the Massachusetts Securities Division of the Secretary of the Commonwealth of Massachusetts (MSD) requesting corporate documents concerning, among other topics, the allegations raised by the Securities Class Action and the Shareholder Demand. The Company responded to the MSD's subpoena on September 22, 2014 and October 8, 2014. On February 18, 2015, the Company received a second subpoena from the MSD requesting additional documents and information related to the same topics. The Company responded to this second subpoena on March 24, 2015. On October 21, 2015, the Company received a letter from the SEC notifying the Company that it had concluded its investigation of the Company and that it did not intend to recommend an enforcement action against the Company.

The Company intends to continue to defend itself against these claims and, to date, has not recorded any provision for losses that may arise.

**6. ACCRUED EXPENSES**



Accrued expenses consisted of the following (in thousands):

|                        | <b>June 30,<br/>2016</b> | <b>December 31,<br/>2015</b> |
|------------------------|--------------------------|------------------------------|
| Accrued bonus          | \$ 613                   | \$ 85                        |
| Accrued payroll        | 80                       | 81                           |
| Accrued vacation       | 222                      | 208                          |
| Other accrued expenses | 254                      | 374                          |
| Total accrued expenses | \$ 1,169                 | \$ 374                       |

## 7. **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

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of capital equipment. The annual interest rate on the loan 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 \$41 became due commencing on May 1, 2015. Remaining principal payments for the years ending December 31, 2016, 2017, 2018 and 2019 are \$201, \$423, \$452 and \$400, respectively.

Also in October 2012, in connection with the loan agreement, the Company issued MassDev a warrant for the purchase of 9,037 shares of the Company's 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 which commenced in October 2012. Amortization of the deferred financing cost for the three months and six months ended June 30, 2016 was \$1 and \$2, respectively, 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 three months ended June 30, 2016 and 2015 was \$26 and \$31, respectively. Interest expense related to this loan for the six months ended June 30, 2016 and 2015 was \$53 and \$62, respectively.

## 8. COMMON STOCK

The Company has authorized 100,000,000 shares of common stock, \$0.00001 par value per share, of which 31,917,308 shares were issued and outstanding as of June 30, 2016 and 27,555,948 shares were issued and outstanding as of December 31, 2015.

During the six months ended June 30, 2016, the Company issued an aggregate of 39,412 shares of common stock upon the exercise of stock options and received cash proceeds of approximately \$36.

During the six months ended June 30, 2016, the Company issued an aggregate of 2,220 shares of common stock upon the cashless exercise of warrants.

During the six months ended June 30, 2016, the Company issued an aggregate of 19,447 shares of common stock with a fair value of \$109 to the Company's 401(k) plan as a matching contribution.

During the six months ended June 30, 2016, the Company issued an aggregate of 6,948 shares of common stock under the Company's Employee Stock Purchase Plan and received cash proceeds of approximately \$43.

In March 2016, the Company closed an underwritten public offering of an aggregate of 4,293,333 shares of common stock and warrants to purchase an aggregate of 2,146,666 shares of common stock, at a price to the public of \$7.49 per share of common stock and \$0.01 per warrant. The net proceeds to the Company, after deducting underwriting discounts and offering expenses, were approximately \$29,905. The warrants have a per share exercise price of \$10.00, or approximately 133% of the public offering price of the common stock, are exercisable immediately, and expire on March 18, 2021. The Company intends to use the net proceeds from the offering to fund ongoing clinical trials and for general

corporate purposes.

During the year ended December 31, 2015, the Company issued an aggregate of 316,177 shares of common stock upon the exercise of stock options, including stock options to purchase 52,224 shares of common stock exercised through cashless exercise provisions, resulting in the issuance of 14,961 shares of common stock and stock options to purchase 301,216 shares of common stock exercised for cash, providing cash proceeds of \$1,068.

During the year ended December 31, 2015, the Company issued an aggregate of 1,379,575 shares of common stock upon the exercise of warrants, including warrants to purchase 40,955 shares of common stock exercised through cashless exercise provisions, resulting in the issuance of 25,052 shares of common stock and warrants to purchase 1,354,523 shares of common stock exercised for cash, providing net cash proceeds of \$7,789.

During the year ended December 31, 2015, the Company issued an aggregate of 17,437 shares of common stock with a fair value of \$201 to the Company's 401(k) plan as a matching contribution.

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 Company's 1-for-4 reverse stock split on its common stock on April 8, 2015, 1,514 shares of common stock were issued to account for the fractional roundup of shareholders.

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**9. STOCK OPTIONS**

In 2007, the Company adopted, and the Company's shareholders subsequently approved, 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.

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 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.

In April 2015, the Company's Board of Directors adopted, and the Company's shareholders subsequently approved, the 2015 Equity Incentive Plan (the 2015 Plan). The 2015 Plan provides for grants of incentive stock options to employees and nonqualified stock, restricted common stock, restricted stock units and stock appreciation rights to employees, consultants and non-employee directors of the Company. Upon approval of the 2015 Plan by the Company's shareholders in June 2015, the 2010 Plan was terminated and no additional shares or share awards have been subsequently granted under the 2010 Plan. As of June 30, 2016, the total number of shares authorized for issuance under the 2015 Plan was 4,322,355 shares, consisting of 4,000,000 initially approved under the 2015 Plan shares plus the 322,355 shares that remained available for grant under the 2010 Plan at the time of its termination.

Options issued under the 2007 Plan, the 2010 Plan, and the 2015 Plan (collectively, the Plans) are exercisable for up to 10 years from the date of issuance. As of June 30, 2016, there were outstanding options to purchase an aggregate of 3,152,775 shares of common stock under the Plans, consisting of 205,863 shares under the 2007 Plan, 1,896,652 shares under the 2010 Plan and 1,050,260 shares under 2015 Plan. As of December 31, 2015, there were outstanding options to purchase an aggregate of 946,760, 2,065,687 and 240,863 shares of common stock under the 2015 Plan, 2010 Plan and 2007 Plan, respectively.

In March 2015, the Company's Board of Directors adopted, and the Company's shareholders subsequently approved, the Employee Stock Purchase Plan (the ESPP). The ESPP 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 for issuance under the ESPP. Commencing on the first day of 2016 and on the first day of each year thereafter during the term of the ESPP, the number of shares of common stock reserved for issuance were and shall be increased by the lesser of (i) 1% of the Company's outstanding shares of common stock on such date, (ii) 50,000 shares or (iii) a lesser amount determined by the Board of Directors. Under the terms of the ESPP, in no event shall the aggregate number of shares reserved for issuance during the term of the ESPP exceed 1,250,000 shares. On January 1, 2016, the reserve was increased by 50,000 shares in accordance with the ESPP increase provisions.

In January 2016, 6,948 shares that were purchased in the offering period commencing on July 1, 2015 and ending on December 31, 2015 were issued under the ESPP. The ESPP is considered a compensatory plan with the related compensation cost recognized over each six month offering period. As of June 30, 2016, \$48 of employee payroll deductions have been withheld since December 31, 2015, the commencement of the current offering period, and are included in accrued expenses in the accompanying balance sheet. The compensation expense related to the ESPP for the three and six months ended June 30, 2016 was \$16 and

\$27, respectively, and is included in stock-based compensation expense.

*Share-based compensation (in thousands)*

For the three months ended June 30, 2016 and 2015, the Company recorded non-cash, stock-based compensation expense of approximately \$1,244 and \$976, respectively, net of forfeitures. For the six months ended June 30, 2016 and 2015, the Company recorded non-cash, stock-based compensation expense of approximately \$2,396 and \$2,241, respectively, net of forfeitures. Stock-based compensation expense for the three and six months ended June 30, 2016 includes \$112 of expense related to a stock option modification.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model. 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, 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.

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A summary of option activity as of June 30, 2016 and changes for the six month period then ended are presented below:

| Options                                      | Shares    | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term in<br>Years | Aggregate<br>Intrinsic Value |
|--|-----------|--|---|------------------------------|
| Outstanding at December 31, 2015             | 3,253,310 | \$ 7.47                                  |   |                              |
| Granted                                      | 107,500   | \$ 6.35                                  |   |                              |
| Forfeited                                    | (168,623) | \$ 9.59                                  |   |                              |
| Exercised                                    | (39,412)  | \$ 0.92                                  |   |                              |
| Outstanding at June 30, 2016                 | 3,152,775 | \$ 7.40                                  | 7.70  | \$ 1,975                     |
| Vested at June 30, 2016                      | 1,462,311 | \$ 7.01                                  | 6.40  | \$ 1,584                     |
| Vested and expected to vest at June 30, 2016 | 2,590,789 | \$ 7.33                                  | 7.45  | \$ 1,831                     |

The weighted average grant-date fair value of options granted during the six months ended June 30, 2016 was \$5.30 per share. The total fair value of options that vested for the six months ended June 30, 2016 was approximately \$2,108. The total fair value of options that vested for the three months ended June 30, 2016 was approximately \$878. As of June 30, 2016, there was approximately \$6,752 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 2.58 years at June 30, 2016.

## 10. WARRANTS

The following table presents information about warrants to purchase common stock issued and outstanding at June 30, 2016:

| Year Issued                     | Classification | Number of<br>Warrants | Exercise Price | Date of Expiration   |
|---------------------------------|----------------|-----------------------|----------------|----------------------|
| 2010                            | Equity         | 343,931               | \$ 5.60        | 10/26/2017 12/3/2017 |
| 2010                            | Equity         | 314,059               | \$ 4.00        | 8/30/2017 12/3/2017  |
| 2011                            | Equity         | 85,785                | \$ 12.24       | 12/21/2016           |
| 2012                            | Equity         | 6,054                 | \$ 6.64        | 10/5/2019            |
| 2014                            | Liability      | 587,950               | \$ 3.87        | 5/9/2019             |
| 2016                            | Equity         | 2,146,666             | \$ 10.00       | 3/18/2021            |
| Total                           |                | 3,484,445             |                |                      |
| Weighted average exercise price |                |                       | \$ 8.04        |                      |
| Weighted average life in years  |                |                       |                | 3.66                 |

In March 2016, the Company closed an underwritten public offering of an aggregate of 4,293,333 shares of common stock and warrants to purchase an aggregate of 2,146,666 shares of common stock, at a price to the public of \$7.49 per share of common stock and \$0.01 per warrant.

The warrants have an initial per share exercise price of \$10.00 (133% of public offering price of the common stock) and will expire on March 18, 2021. The warrants are immediately exercisable, at the option of each holder, in whole or in part, in cash or through a cashless exercise as discussed below. The exercise price and number of shares of common stock issuable upon exercise of the warrants are subject to adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, or similar transaction, among other events as described in the warrants. In the event that shares of common stock underlying the warrants are no longer registered under the Securities Exchange Act of 1934, as amended, the holder may, in its sole discretion, exercise the warrant in whole or in part and, in lieu of making cash payment, elect instead to receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant.

The fair value of the warrants was estimated at \$11,726 using a Black-Scholes model with the following assumptions: expected volatility of 112.82%, risk free interest rate of 1.34%, expected life of five years and no dividends.

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The Company assessed whether the warrants require accounting as derivatives. The Company determined that the warrants were (1) indexed to the Company's own stock and (2) classified in stockholders' equity in accordance with FASB Accounting Standards Codification (ASC) Topic 815, *Derivatives and Hedging*. As such, the Company has concluded that the warrants meet the scope exception for determining whether the instruments require accounting as derivatives and should therefore instead be classified as stockholders' equity.

**11. DERIVATIVE INSTRUMENTS**

In May 2014, in connection with a public offering, the Company issued warrants that have anti-dilution protection provisions that allow for a 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 three months ended June 30, 2016 and 2015 a gain (loss) of \$595 and \$(4,653), respectively, was included in other income (expense) in the Company's consolidated statement of operations. For the six months ended June 30, 2016 and 2015 a loss of \$(452) and \$(14,940), respectively, was included in other income (expense) in the Company's consolidated statement of operations. The assumptions used principally in determining the fair value of the warrants were as follows:

|                          | June 30,<br>2016 | December 31,<br>2015 |
|--------------------------|------------------|----------------------|
| Risk-free interest rate  | 0.71%            | 0.65%                |
| Expected dividend yield  | 0.00%            | 0.00%                |
| Expected term (in years) | 2.86             | 3.36                 |
| Expected volatility      | 106.30%          | 100.20%              |

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 three and six months ended June 30, 2016 and 2015 are as follows (in thousands):

|  | Three Months Ended June 30, |           |
|--|-----------------------------|-----------|
|  | 2016                        | 2015      |
| Balance at March 31,   | \$ 2,954                    | \$ 12,644 |
| Fair value of warrants issued  |                             |           |
| Reduction in derivative liability due to exercise and modification of warrants |                             | (9,575)   |
| (Decrease) increase in the fair value of warrants                              | (595)                       | 4,653     |
| Balance at June 30,  | \$ 2,359                    | \$ 7,722  |

|  | Six Months Ended June 30, |      |
|--|---------------------------|------|
|  | 2016                      | 2015 |



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|  |    |       |    |          |
|--|----|-------|----|----------|
| Balance at December 31,  | \$ | 1,907 | \$ | 7,224    |
| Fair value of warrants issued  |    |       |    |          |
| Reduction in derivative liability due to exercise and modification of warrants |    |       |    | (14,442) |
| Increase in the fair value of warrants   |    | 452   |    | 14,940   |
| Balance at June 30,  | \$ | 2,359 | \$ | 7,722    |

The March 2016 public offering resulted in a repricing of the Company's liability-classified warrants. The liability-classified warrants' prices were decreased from \$5.75 per share to \$3.87 per share. In addition, the number of shares subject to the warrants increased from 395,716 to 587,950. The decline in the warrant liability for the three months ended June 30, 2016 is primarily driven by the decrease in the fair value of the underlying stock price since March 31, 2016. The increase in the liability for the six months ended June 30, 2016 was due to the issuance of additional warrants issued in connection with the repricing of liability-classified warrants, partially offset by the decrease in the fair value of the underlying stock price since December 31, 2015.

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**12. SUBSEQUENT EVENTS**

The Company has evaluated all events and transactions that occurred after the balance sheet date through the date of this filing. During this period, the Company did not have any material subsequent events that impacted its financial statements or disclosures other than already disclosed in these notes to the financial statements.

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**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, 2015 (the 2015 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 commercialization strategy, future operations, cash requirements and liquidity, 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 may, might, will, should, 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 raise substantial additional capital to finance our planned operations and to continue as a going concern, 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 2015 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 treatment of spinal cord injuries (SCI). Our mission is to redefine the life of the SCI patient, and we are developing treatment options intended to provide meaningful improvement in patient outcomes following SCI. Our approach to treating acute SCI is based on our investigational *Neuro-Spinal Scaffold* implant, a 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. We believe that the *Neuro-Spinal Scaffold* is the only SCI therapy in development focused solely on treating acute SCI directly at the epicenter of the injury. The *Neuro-Spinal Scaffold* incorporates intellectual property licensed under an exclusive, worldwide license from Boston Children's Hospital (BCH) and the Massachusetts Institute of Technology (MIT). We are continually evaluating other technologies and therapeutics that may be complementary to our development of the *Neuro-Spinal Scaffold* or offer the potential to bring us closer to our goal of redefining the life of the SCI patient.

**Our Clinical and Pre-Clinical Programs**

We currently have a clinical development program for acute SCI and a pre-clinical development program for chronic SCI.

*Neuro-Spinal Scaffold Implant for acute SCI*

Our leading product under development is our *Neuro-Spinal Scaffold*, an investigational bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord contusion. The *Neuro-Spinal Scaffold* is intended to provide support to the surrounding tissue after injury, minimizing expansion areas of necrosis, and supporting endogenous healing/repair processes following injury. This form of appositional healing harbors the promise of sparing white matter, increasing neural sprouting, and diminishing post-traumatic cyst formation.

The *Neuro-Spinal Scaffold* is composed of two biocompatible and bioresorbable polymers that are cast to form a highly porous investigational product:

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- Poly lactic-co-glycolic acid (PLGA), a polymer that is widely used in resorbable sutures and provides the biocompatible support for *Neuro-Spinal Scaffold*; and
- Poly-L-Lysine (PLL), a positively charged polymer commonly used to coat surfaces in order to promote cellular attachment.

We expect the *Neuro-Spinal Scaffold* will be regulated by the U.S. Food & Drug Administration ( FDA ) as a Class III medical device when used as a standalone product.

In late 2015, we completed the early feasibility pilot cohort of the *Neuro-Spinal Scaffold* study under an approved Investigational Device Exemption application for the treatment of complete, traumatic acute spinal cord injury. The objective of the pilot study cohort was to establish 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*.

In January 2016, the FDA approved converting the pilot study of the *Neuro-Spinal Scaffold* into a pivotal probable benefit study formally known as The **INSPIRE** Study: **In**Vivo Study of Probable Benefit of the *Neuro-Spinal Scaffold* for Safety and Neurologic **R**ecovery in Subjects with Complete Thoracic AIS A Spinal Cord Injury. The purpose of the study is to evaluate whether the *Neuro-Spinal Scaffold* is safe and demonstrates probable benefit for the treatment of complete T2-T12/L1 spinal cord injury. The primary endpoint is defined as the proportion of patients achieving an improvement of at least one American Spinal Injury Association Impairment Scale ( AIS ) grade by six months post-implantation. Additional endpoints include a reduction in pain and improvements in sensory and motor scores, bladder and bowel function, Spinal Cord Independence Measure and quality of life.

After review of the six-month pilot data package, the FDA approved The INSPIRE study to expand enrollment from 12 to up to 30 patients. There are currently 21 U.S. clinical sites and one Canadian clinical site participating in The INSPIRE Study

In February 2016, we received approval of a protocol amendment for The INSPIRE Study. The amended protocol establishes the Objective Performance Criterion ( OPC ), which is a measure of study success used in clinical studies designed to demonstrate safety and probable benefit in support of a Humanitarian Device Exemption ( HDE ) approval. The OPC for The INSPIRE Study is defined as 25% or more of the patients in the study demonstrating an improvement of at least one AIS grade by six months post-implantation. Although our OPC is the fundamental component to demonstrate probable benefit, the OPC is not the only variable that the FDA evaluates when reviewing an HDE application. Approval is not guaranteed if the OPC is met, and even if the OPC is not met, the FDA may approve a therapy if probable benefit is supported by a comprehensive review of all clinical endpoints and preclinical results, as demonstrated by the sponsor's body of evidence. Since The INSPIRE Study is designed to enroll 20 patients with complete (AIS A) spinal cord injuries (inclusive of the five patients enrolled in the company's pilot trial), the OPC equates to having five evaluable patients convert to any other AIS grade by six months post-implantation. During the interactions regarding the approval of the expansion of The INSPIRE study to enroll up to 30 patients, the FDA recommended that we include a control arm in the study as part of a study design consideration. At the present time, we are in discussions with the FDA regarding this recommendation.

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We are targeting completion of the study, which includes completion of enrollment, follow-up, and submission of the HDE application, in 2017.

In late February 2016, the FDA accepted our proposed HDE modular shell submission and review process for the *Neuro-Spinal Scaffold*. The HDE modular shell is comprised of three modules, a preclinical studies module, a manufacturing module, and a clinical data module. As part of its review process, the FDA reviews modules, which are individual sections of the HDE submission, on a rolling basis. Following the submission of each module, the FDA reviews and provides feedback, typically within 90 days, allowing the applicant to receive feedback and potentially resolve any deficiencies during the review process. Upon receipt of the final module, which constitutes the complete HDE submission, the FDA will make a filing decision which may trigger the review clock for an approval decision.

In March 2016, we announced that the fifth patient in The INSPIRE Study had improved from complete AIS A spinal cord injury to an incomplete AIS B spinal cord injury between the three-month and the six-month post-injury assessment. In April 2016, we announced that the sixth patient in The INSPIRE Study had improved from complete AIS A spinal cord injury to an incomplete AIS B spinal cord injury between the one-month and the two-month post-injury assessment. Also in April 2016, we announced that the eighth patient enrolled into The INSPIRE Study died after injuries from a severe motor vehicle accident and unrelated to the investigational product. In July 2016, the ninth and tenth patients were enrolled into The INSPIRE study. The tenth patient died from a stroke, which was unrelated to the investigational product.

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*Bioengineered Neural Trails injection program for chronic SCI*

In December 2015, we announced our preclinical Bioengineered Neural Trails injection program for the treatment of chronic spinal cord injury. Bioengineered Neural Trails are injectable combinations of biomaterials and neural stem cells delivered using minimally-invasive surgical instrumentation and techniques to create trails across the chronic injury site. To support this program, we entered into an exclusive license agreement with the University of California, San Diego and an assignment agreement with James Guest, M.D., Ph.D., for issued patents covering technology related to the Bioengineered Neural Trails program, and we also have filed a provisional application in support of the Bioengineered Neural Trails injection program. We expect that our Bioengineered Neural Trails injection investigational product will be regulated by the FDA as a combination product, and we are targeting a pre-Investigational New Drug meeting with the FDA by the end of 2016.

Overall, we expect our research and development 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. While we are currently focused on advancing the *Neuro-Spinal Scaffold* and the Bioengineered Neural Trails injection program, our research and development 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. 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.

We incorporated under the laws of the state of Nevada on April 2, 2003 as Design Source, Inc. On October 26, 2010, we acquired the business of InVivo Therapeutics Corporation, which was founded in 2005, and are continuing the existing business operations of InVivo Therapeutics Corporation as our wholly-owned subsidiary. We changed our name to InVivo Therapeutics Holdings Corp. in connection with the acquisition.

**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 2015 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.

## Results of Operations

### *Comparison of the Three Months Ended June 30, 2016 and 2015 (in thousands)*

#### 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 June 30, 2016 were \$2,795, an increase of \$249 compared to the three months ended June 30, 2015. The increase in research and development expenses for the three months ended June 30, 2016 is primarily attributed to higher salaries and associated benefits costs of \$31, reflecting the full year impact of new hires. In addition, clinical trial costs rose \$113 due to an increase in the number of patients in the trial and the opening of additional clinical trial sites. Higher outside services costs of \$207, consulting costs of \$49 and other expenses of \$15 also contributed to the increase. Partly offsetting these cost increases was a reduction in stock compensation expense of \$97 and lower recruiting costs of \$69.



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**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 June 30, 2016 were \$2,991, a decrease of \$223 compared to the three months ended June 30, 2015. The decline in general and administrative expenses for the three months ended June 30, 2016 is attributed to reduced legal expenses of \$740 and lower NASDAQ filing fees of \$52 and other expenses of \$36. These decreases were partly offset by higher stock compensation costs of \$364, higher salaries and associated benefits of \$65 and higher convention costs of \$176.

**Other Income and Expense**

Other income for the three months ended June 30, 2016 was \$602, which was comprised of interest income of \$36, interest expense of \$29 and a derivative gain of \$595. The three months ended June 30, 2016 reflected a decrease in expense of \$5,285 compared to the three months ended June 30, 2015, primarily related to the change in the derivative warrant liability of \$5,248.

*Comparison of the Six Months Ended June 30, 2016 and 2015 (in thousands)*

**Research and Development Expenses**

Research and development expenses consisted primarily of payments to contract research organizations and payroll. Research and development expenses for the six months ended June 30, 2016 were \$5,364, an increase of \$516 compared to the six months ended June 30, 2015. The increase in research and development expenses for the six months ended June 30, 2016 is primarily attributed to higher salaries and associated benefits costs of \$262, reflecting the full year impact of new hires. In addition, clinical trial costs rose \$222 due to an increase in the number of patients in the trial and the opening of additional clinical trial sites. Higher outside service costs of \$265 and other expenses of \$9 contributed to this increase compared to the same period in the prior year. Partly offsetting these cost increases was a reduction in stock compensation expense of \$173 and lower recruiting costs of \$69.

**General and Administrative Expenses**

General and administrative expenses consisted primarily of payroll, rent and professional services. General and administrative expenses for the six months ended June 30, 2016 were \$5,990, a decrease of \$432 compared to the six months ended June 30, 2015. The decline in general and administrative expenses for the six months ended June 30, 2016 is attributed to reduced legal expenses of \$1,328 and other expenses of \$5. These decreases were offset by higher consulting fees of \$141, conventions costs of \$175,

stock compensation costs of \$328, higher salaries and associated benefits of \$190 and audit fees of \$67.

#### **Other Income and Expense**

Other expense for the six months ended June 30, 2016 was \$453, which was comprised of interest income of \$91, interest expense of \$92 and a derivative loss of \$452. The six months ended June 30, 2016 reflected a decrease in expense of \$14,550 compared to the six months ended June 30, 2015, primarily related to the change in the derivative warrant liability of \$14,488.

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

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 June 30, 2016, we had total assets of \$43,510 and total liabilities of \$5,899, resulting in stockholders' equity of \$37,611. The Company also recorded a net loss of \$11,807 for the six months ended June 30, 2016.

We have historically financed our operations primarily through the sale of equity securities. In March 2016, we closed an underwritten public offering of an aggregate of 4,293,333 shares of common stock and warrants to purchase an aggregate of 2,146,666 shares of common stock, at a price to the public of \$7.49 per share of common stock and \$0.01 per warrant. The underwriting discount was 6% of the public offering price of the shares, or \$0.45 per share and 0.0000006 per warrant. The warrants have an initial per share exercise price of \$10.00 (133% of public offering price of the common stock) and will expire on March 18, 2021.

We believe our current cash and cash equivalents are adequate to fund our operations through the end of 2017. At June 30, 2016, we had cash of approximately \$41,629.

Net cash used in operating activities for the six months ended June 30, 2016 was approximately \$8,282, as compared to net cash used in operating activities of approximately \$7,147 for the six months ended June 30, 2015. The change in net cash used in operating activities for the six months ended June 30, 2016 as compared to the same period in the prior year was primarily due to an insurance

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settlement received in the first quarter of 2015. 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 \$3,011. Total commitments due for the remainder of fiscal 2016 under operating leases are approximately \$633.

Net cash used in investing activities for the six months ended June 30, 2016 totaled approximately \$73 for purchases of capital equipment. There was no comparable spending in 2015.

Net cash provided by financing activities was approximately \$29,790 for the six months ended June 30, 2016 primarily consisting of the proceeds from our March 2016 offering, as compared to net cash provided by financing activities of approximately \$18,802 for the six months ended June 30, 2015, which was primarily related to proceeds from our January 2015 offering and from warrant exercises.

In July 2015, we entered into a Sales Agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen") pursuant to which we 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 agreed to act as our sales agent. We did not make any sales under the Sales Agreement in 2016 and the Sales Agreement was terminated in March 2016.

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 \$150 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 registration statement 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.

We may pursue various other dilutive and non-dilutive funding alternatives upon the results of our ongoing pivotal probable benefit study and the extent to which we require additional capital to proceed with development of some or all of our product candidates on expected timelines. The source, timing and availability of any future financing will depend principally upon market conditions and the status of our 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 trials, and our capital expenditures or to license our potential products or technologies to third parties.

**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 2015 Annual Report. As of June 30, 2016 there were no material changes in exposure to market risk from December 31, 2015.

**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 June 30, 2016. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures as of June 30, 2016 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**

There have been no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings.**

*Lawsuits 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, and corporate waste, and seeks monetary damages and an accounting. The lawsuit involves approximately \$500 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 related to Mr. Reynolds's allegations that the Company and the Board of Directors 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 that he did not receive. On January 9, 2014, the Company, along with the directors named in the counterclaims, filed its answer. No judgments or rulings are pending at this stage.

On July 22, 2016, Mr. Reynolds filed a lawsuit against the Company, certain present and former members of the Company's Board of Directors and an employee of the Company in Hillsborough County Superior Court, Southern District, Hillsborough County, New Hampshire (*Reynolds v. InVivo Therapeutics Holdings Corp, et al.*) alleging defamation, conspiracy and tortious interference, and seeking monetary damages.

*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* implant. The plaintiff sought 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.

On May 4, 2015, the plaintiff filed a notice of appeal of this decision. A mandatory mediation conference was held on September 10, 2015. Following that conference, on October 5, 2015, the plaintiff/appellant filed his opening brief with the United States Court of Appeals for the First Circuit. The Company and the individual defendants/appellees filed their answering brief on November 5, 2015, and the plaintiff/appellant filed his reply brief on December 10, 2015. The Court of Appeals heard oral arguments on April 6, 2016.

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On January 23, 2015, Shawn Luger, a purported shareholder of the Company, sent the Company a letter (the "Shareholder Demand") demanding that the Board of Directors take action to remedy purported breaches of fiduciary duties allegedly related to the claimed false and misleading statements that are the subject of the Securities Class Action. The Board of Directors 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, Mr. Luger filed a shareholder derivative lawsuit in the Superior Court of Suffolk County for the Commonwealth of Massachusetts on behalf of the Company against certain present and former board members and company executives alleging the same breaches of fiduciary duties purportedly set forth in the Shareholder Demand. On February 5, 2016, the Superior Court of Suffolk County dismissed the plaintiff's claims with prejudice. On March 4, 2016, the plaintiff filed a notice of appeal of this decision. On June 15, 2016, plaintiff/appellant filed his opening brief with the Appeals Court of the Commonwealth of Massachusetts. The Company and the individual defendants/appellees filed their answering brief on July 15, 2016. Plaintiff/appellant's reply brief is due on July 29, 2016.

In addition to the derivative lawsuit and the appeal of the Securities Class Action, the Company received investigation subpoenas from the Boston Regional Office of the SEC and the Massachusetts Securities Division of the Secretary of the Commonwealth of Massachusetts ("MSD") requesting corporate documents concerning, among other topics, the allegations raised by the Securities Class Action and the Shareholder Demand. The Company responded to the MSD's subpoena on September 22, 2014 and October 8, 2014. On February 18, 2015, the Company received a second subpoena from the MSD requesting additional documents and information related to the same topics. The Company responded to this second subpoena on March 24, 2015. On October 21, 2015, the Company

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received a letter from the SEC notifying the Company that it had concluded its investigation of the Company and that it did not intend to recommend an enforcement action against the Company.

The Company intends to continue to defend itself against these claims and, to date, has not recorded any provision for losses that may arise.

**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 2015 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 on Form 10-Q.



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**SIGNATURES**

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

**INVIVO THERAPEUTICS HOLDINGS CORP.**

Date: August 4, 2016

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

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**EXHIBIT INDEX**

| <b>Exhibit<br/>Number</b> | <b>Description</b>  |
|---------------------------|---|
| 3.1                       | Articles of Incorporation of InVivo Therapeutics Holding Corp., as amended                                  |
| 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  |