

INVIVO THERAPEUTICS HOLDINGS CORP.

Form 10-Q

May 12, 2014

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**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 March 31, 2014.

or

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

For the transition period from to .

Commission File Number: 000-52089

InVivo Therapeutics Holdings Corp.

(Exact name of registrant as specified in its charter)

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

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

As of May 9, 2014, 93,022,289 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 March 31, 2014

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Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements.****InVivo Therapeutics Holdings Corp.****(A Development Stage Company)****Consolidated Balance Sheets****(In thousands, except share and per share data)****(Unaudited)**

| | March 31, 2014 | As of | December 31, 2013 |
|---|---------------------------|--------------|------------------------------|
| ASSETS: | | | |
| Current assets: | | | |
| Cash and cash equivalents | \$ 9,846 | \$ | 13,980 |
| Restricted cash | 371 | | 602 |
| Prepaid expenses | 445 | | 20 |
| Total current assets | 10,662 | | 14,602 |
| Property, equipment and leasehold improvements, net | 2,182 | | 2,337 |
| Other assets | 152 | | 157 |
| Total assets | \$ 12,996 | \$ | 17,096 |
| LIABILITIES AND STOCKHOLDERS EQUITY: | | | |
| Current liabilities: | | | |
| Accounts payable | \$ 704 | \$ | 899 |
| Note payable-current portion | 74 | | 74 |
| Capital lease payable | | | 3 |
| Accrued expenses | 1,236 | | 1,292 |
| Total current liabilities | 2,014 | | 2,268 |
| Loan payable | 1,920 | | 1,920 |
| Note payable-less current portion | | | 18 |
| Total liabilities | 3,934 | | 4,206 |
| Commitments and Contingencies | | | |

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Stockholders' equity:

| | | | | |
|---|-----------|---------------|-----------|---------------|
| Common stock, \$0.00001 par value, authorized 200,000,000 shares at March 31, 2014 and December 31, 2013; issued and outstanding 79,021,039 and 78,773,736 shares at March 31, 2014 and December 31, 2013, respectively | | 1 | | 1 |
| Additional paid-in capital | | 96,073 | | 94,798 |
| Deficit accumulated during the development stage | | (87,012) | | (81,909) |
| Total stockholders' equity | | 9,062 | | 12,890 |
| Total liabilities and stockholders' equity | \$ | 12,996 | \$ | 17,096 |

See notes to the consolidated financial statements.

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

| | Three Months Ended | | November 28, |
|---|---------------------------|--------------------|-----------------------|
| | March 31, | | 2005 |
| | 2014 | 2013 | (inception) to |
| | | | March 31, |
| | | | 2014 |
| Operating expenses: | | | |
| Research and development | \$ 3,242 | \$ 1,213 | \$ 29,035 |
| General and administrative | 1,829 | 1,638 | 24,956 |
| Total operating expenses | 5,071 | 2,851 | 53,991 |
| Operating loss | (5,071) | (2,851) | (53,991) |
| Other income (expense): | | | |
| Other income | | | 383 |
| Interest income | 1 | 3 | 72 |
| Interest expense | (33) | (29) | (1,301) |
| Modification of warrants | | | (765) |
| Derivatives loss | | (10,449) | (31,410) |
| Other expense, net | (32) | (10,475) | (33,021) |
| Net loss | \$ (5,103) | \$ (13,326) | \$ (87,012) |
| Net loss per share, basic and diluted | \$ (0.07) | \$ (0.20) | \$ (2.11) |
| Weighted average number of common shares outstanding, basic and diluted | 74,162,786 | 66,043,378 | 41,269,131 |

See notes to the consolidated financial statements.

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

| | Three Months Ended March 31, | | Period from November 28, 2005 (inception) to March 31, 2014 |
|---|---------------------------------|----------------|---|
| | 2014 | 2013 | |
| Cash flows from operating activities: | | | |
| Net loss | \$ (5,103) | \$ (13,326) | \$ (87,012) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization expense | 195 | 167 | 1,540 |
| Non-cash derivatives loss | | 10,449 | 31,410 |
| Non-cash interest expense | | | 985 |
| Non-cash loss from modification of warrants | | | 765 |
| Common stock issued to 401(k) plan | 41 | 53 | 366 |
| Common stock issued for services | 282 | | 516 |
| Share-based compensation expense | 835 | 432 | 7,004 |
| Changes in operating assets and liabilities: | | | |
| Restricted cash | 231 | | (371) |
| Prepaid expenses | (425) | (63) | (456) |
| Other assets | 1 | 1 | (194) |
| Accounts payable | (195) | (70) | 704 |
| Accrued interest payable | | | (15) |
| Accrued expenses | (56) | (312) | 1,236 |
| Net cash used in operating activities | (4,194) | (2,669) | (43,522) |
| Cash flows from investing activities: | | | |
| Purchases of property and equipment | (35) | (410) | (3,555) |
| Net cash used in investing activities | (35) | (410) | (3,555) |
| Cash flows from financing activities: | | | |
| Proceeds from issuance of note payable | | | 150 |
| Repayment of note payable | (18) | | (75) |
| Proceeds from issuance of convertible notes payable | | | 4,181 |
| Proceeds from convertible bridge notes | | | 500 |
| Principal payments on capital lease obligation | (3) | (8) | (94) |
| Proceeds from loan payable | | 222 | 2,241 |
| Repayment of loan payable net | | | (321) |
| Proceeds from exercise of options and warrants | 116 | 341 | 50,341 |
| Net cash provided by financing activities | 95 | 555 | 56,923 |

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| | | | |
|--|----------|-----------|----------|
| Increase in cash and cash equivalents | (4,134) | (2,524) | 9,846 |
| Cash and cash equivalents at beginning of period | 13,980 | 12,825 | |
| Cash and cash equivalents at end of period | \$ 9,846 | \$ 10,301 | \$ 9,846 |

See notes to the consolidated financial statements.

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

| | Three Months Ended, March 31, | | 2013 | Period from November 28, 2005 (inception) to March 31, 2014 |
|--|----------------------------------|----|------|--|
| | 2014 | | | |
| Supplemental disclosure of cash flow information and non-cash transactions: | | | | |
| Cash paid for interest | \$ | 32 | \$ | 27 \$ |
| | | | | 313 |
| Conversion of convertible notes payable and accrued interest into common stock | \$ | | \$ | \$ |
| | | | | 4,672 |
| Conversion of convertible bridge note payable and accrued interest into common stock | \$ | | \$ | \$ |
| | | | | 505 |
| Asset acquired through capital lease obligation | \$ | | \$ | \$ |
| | | | | 94 |
| Beneficial conversion feature on convertible and bridge notes payable | \$ | | \$ | \$ |
| | | | | 134 |
| Fair value of warrants issued with bridge notes payable | \$ | | \$ | \$ |
| | | | | 179 |
| Fair value of warrants issued in connection with loan agreement | \$ | | \$ | \$ |
| | | | | 42 |
| Reclassification of derivative warrant liability to additional paid-in capital | \$ | | \$ | 476 \$ |
| | | | | 38,104 |

See notes to the consolidated financial statements.

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Notes to Consolidated Financial Statements for the Quarter Ended March 31, 2014 (Unaudited)

1. NATURE OF OPERATIONS, BASIS OF PRESENTATION, AND GOING CONCERN

Business

InVivo Therapeutics Corporation (InVivo or the Company) was incorporated on November 28, 2005 under the laws of the State of Delaware. The Company develops novel biomaterial technologies for the treatment of spinal cord injuries and hydrogels for therapeutics delivery. Its proprietary technologies incorporates intellectual property licensed under the Company's exclusive, world-wide license from Children's Medical Center Corporation (CMCC) and the Massachusetts Institute of Technology (MIT), and intellectual property that has been developed internally, including in collaboration with its advisors and partners.

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

Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States (GAAP) consistent with those applied in, and should be read in conjunction with, the Company's audited financial statements and related footnotes for the year ended December 31, 2013 included in the Company's Annual Report on Form 10-K as filed with the United States Securities and Exchange Commission (SEC) on March 17, 2014 and amended on April 29, 2014. The unaudited consolidated financial statements reflect all adjustments, consisting only of normal recurring adjustments, which are, in the opinion of management, necessary for a fair presentation of the Company's financial position as of March 31, 2014 and its results of operations and cash flows for the interim periods presented and are not necessarily indicative of results for subsequent interim periods or for the full year. The interim financial statements do not include all of the information and footnotes required by GAAP for complete financial statements as allowed by the relevant SEC rules and regulations; however, the Company believes that its disclosures are adequate to ensure that the information presented is not misleading.

Going Concern

The accompanying financial statements have been prepared on a basis that assumes that the Company will continue as a going concern and that contemplates the continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company has incurred losses since inception in devoting substantially all of its efforts toward research and development and has

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an accumulated loss since inception of \$87,012,000 at March 31, 2014. During the three months ended March 31, 2014, the Company generated a net loss of \$5,103,000, used cash in operations of \$4,194,000, and the Company expects that it will continue to generate operating losses for the foreseeable future. At March 31, 2014, the Company had a cash balance of \$9,846,000. On May 9, 2014, the Company completed an underwritten public offering of an aggregate of 14,001,250 shares of common stock and warrants to purchase an aggregate of 7,000,625 shares of common stock, at a price to the public of \$1.15 per share of common stock and \$0.00001 per warrant. The net proceeds, after deducting underwriting discounts and offering expenses, were approximately \$14.6 million. The Company expects this amount to be sufficient to meet its operating and capital requirements until November 2015. The Company's ability to execute its operating plan beyond November 2015 depends on its ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise. The Company plans to continue to actively pursue additional financing alternatives, but there can be no assurance that it will obtain the necessary funding. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

2. CASH AND CASH EQUIVALENTS

As of March 31, 2014, the Company held \$9,846,000 in cash and cash equivalents. From time to time, the Company may have cash balances in financial institutions in excess of insurance limits. The Company has never experienced any losses related to these balances. The Company's cash equivalents are in money market funds. Cash and cash equivalents consist of the following:

| (In thousands) | March 31, 2014 | December 31, 2013 |
|---------------------------------|-------------------|----------------------|
| Cash | \$ 183 | \$ 219 |
| Money market fund | 9,663 | 13,761 |
| Total cash and cash equivalents | \$ 9,846 | \$ 13,980 |

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3. RESTRICTED CASH

Restricted cash of \$371,000 represented \$60,000 of security deposits related to the Company's credit card account and a \$311,000 cash account securing a standby letter of credit in favor of a landlord (see Note 4).

4. COMMITMENTS AND CONTINGENCIES

Operating Lease Commitment

On November 29, 2011 and as amended on September 17, 2012, the Company entered into a commercial lease for 26,150 square feet of office, laboratory and manufacturing space in Cambridge, Massachusetts (as subsequently amended, the Cambridge Lease). The term of the Cambridge Lease is for six years and three months, with one five-year extension option. The Cambridge Lease also requires a standby letter of credit in the amount of \$311,000 (see Note 3).

The Cambridge Lease contains certain rent escalation clauses. The Company recognizes rent expense on a straight-line basis over the lease term and records the difference between the amount charged to expense and the rent paid as a deferred rent liability. As of March 31, 2014, the amount of deferred rent liability is \$543,000 and is included in accrued expenses.

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

- the lease specifically requires the lessee to make the improvement,
- the improvement is fairly generic,
- the improvement increases the fair value of the property to the lessor, and
- the useful life of the improvement is longer than our lease term.

If any of the above criteria are not met, the Company considers the assets to be lessee assets, which are recorded as leasehold improvements in the Company's consolidated balance sheets and payments received from the lessor to fund any portion of the cost of lessee assets are accounted for as lease incentives. Assets considered to be lessor assets are not reflected in the Company's consolidated balance sheets. To the extent that the Company paid for such lessor assets and was not reimbursed through construction allowances, such net payments are recorded as leasehold improvements, which are amortized to rent expense over the lease term. As of March 31, 2014, such leasehold improvements totaled \$381,000.

Pursuant to the terms of the Company's non-cancelable lease agreements in effect at March 31, 2014, the future minimum rent commitments are as follows:

| Year Ended December 31, (in thousands) | |
|---|-----------------|
| 2014 | 905 |
| 2015 | 1,243 |
| 2016 | 1,269 |
| 2017 | 1,295 |
| 2018 | 1,049 |
| Total | \$ 5,761 |

Total rent expense for the three months ended March 31, 2014 and 2013, including month-to-month leases, was \$287,000 and \$298,000, respectively.

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

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Accrued expenses consisted of the following:

| (In thousands) | March 31, 2014 | December 31, 2013 |
|-------------------------------|-------------------|----------------------|
| Accrued bonus | \$ 419 | \$ 566 |
| Accrued payroll | 118 | 101 |
| Deferred rent payable | 543 | 553 |
| Accrued vacation | 79 | 23 |
| Other accrued expenses | 77 | 49 |
| Total accrued expenses | \$ 1,236 | \$ 1,292 |

6. CAPITAL LEASE PAYABLE

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

| (In thousands) | March 31, 2014 | December 31, 2013 |
|---|-------------------|----------------------|
| Capital lease payable | \$ | \$ 3 |
| Less: current portion | | (3) |
| Capital lease payable, net of current portion | \$ | \$ |

The total value of the laboratory equipment acquired under this capital lease agreement was \$124,000, including a down payment of \$31,000. The capital lease was payable in monthly installments of \$3,000 over a thirty-six month period, with the final payment made in January 2014.

7. NOTE PAYABLE

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

Pursuant to the terms of the non-cancelable purchase agreement in effect at March 31, 2014, the future minimum principal payments are as follows:

Year Ended December 31, (in thousands)

| | | |
|-------|----|----|
| 2014 | | 55 |
| 2015 | | 19 |
| Total | \$ | 74 |

In the third quarter of 2013, the Company abandoned the implementation of the ERP system. As such, the purchase commitment was fully expensed in 2013.

8. LOAN PAYABLE

In October 2012, the Company entered into a loan agreement with the Massachusetts Development Finance Agency (MassDev). The loan agreement provided the Company with a \$2,000,000 line of credit from the Commonwealth of Massachusetts' s Emerging Technology fund, with \$200,000 to be used for working capital purposes and the remainder of which is to be used for the purchase of capital equipment. The annual interest rate is fixed at 6.5% with interest payments only that commenced on November 1, 2012 for the first thirty months and then equal interest and principal payments over the next fifty-four months with the final maturity on October 5, 2019. Based on the \$1,920,000 balance outstanding as of March 31, 2014, equal monthly principal payments of approximately \$36,000 will be due commencing on May 1, 2015. Therefore, for the years ending December 31, 2015, 2016, 2017, 2018 and 2019, principal payments of approximately \$284,000, \$427,000, \$427,000 \$427,000 and \$355,000, respectively, will be due. In September 2012, the Company was assessed commitment fees totaling \$15,000, which was charged to the Company as interest expense. In October 2012, as part of the commitment fee, the Company issued MassDev a warrant for the purchase of 36,145 shares of its Common Stock. The warrant has a seven-year term and is

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exercisable at \$1.66 per share. The fair value of the warrant was determined to be \$32,000 and was recorded as a deferred financing cost and is being amortized to interest expense over a seven-year period commencing in October 2012. Amortization of the deferred financing cost for the three months ended March 31, 2014 was \$1,000 and included in interest expense. 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 March 31, 2014 and 2013 was \$31,000 and \$26,000, respectively.

9. COMMON STOCK

The Company has authorized 200,000,000 shares of Common Stock, \$0.00001 par value per share, of which 79,021,039, shares were issued and outstanding as of March 31, 2014 and 78,773,736 shares were issued and outstanding as of December 31, 2013.

During the three months ended March 31, 2014, the Company issued an aggregate of 52,625 shares of Common Stock upon the exercise of stock options and received cash proceeds of approximately \$104,000.

During the three months ended March 31, 2014, the Company issued an aggregate of 39,900 shares of Common Stock upon the exercise of warrants, including warrants to purchase 62,620 shares of Common Stock exercised through cashless exercise provisions resulting in the issuance of 27,610 shares of Common Stock and warrants to purchase 12,290 shares of Common Stock exercised for cash, providing net cash proceeds of approximately \$12,000.

During the three months ended March 31, 2014, the Company issued an aggregate of 23,556 shares of Common Stock with a fair value of approximately \$41,000 to the Company's 401(k) plan as matching contributions.

During the three months ended March 31, 2014, the Company issued 108,848 and 22,374 shares of Common Stock to Michael J. Astrue, Interim Chief Executive Officer, and Gregory D. Perry, Interim Chief Financial Officer, respectively, in lieu of executive cash bonuses. Such shares had an aggregate fair value of approximately \$282,000.

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 March 31, 2014, there were options to purchase an aggregate of 2,194,607 shares of Common Stock outstanding under the 2007 Plan and no shares available for future grants under the 2007 Plan.

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On October 26, 2010, the Company's Board of Directors adopted and the Company's shareholders subsequently approved the 2010 Equity Incentive Plan (as subsequently amended, the 2010 Plan). The 2010 Plan provides for grants of incentive stock options to employees and nonqualified stock options and restricted Common Stock to employees, consultants and non-employee directors of the Company. As of March 31, 2014, the number of shares authorized for issuance under the 2010 Plan, was 11,000,000 shares. As of March 31, 2014, there were options to purchase an aggregate of 8,237,140 shares of Common Stock outstanding under the 2010 Plan and 2,491,382 shares available for future grants under the 2010 Plan. Options issued under the 2007 Plan and the 2010 Plan are exercisable for up to 10 years from the date of issuance.

Share-based compensation

For stock options issued and outstanding for the three months ended March 31, 2014 and 2013, the Company recorded non-cash, stock-based compensation expense of \$835,000 and \$432,000, respectively, net of forfeitures.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model that uses the assumptions noted in the following table. The Company uses historical data, as well as subsequent events occurring prior to the issuance of the financial statements, to estimate option exercises and employee terminations within the valuation model. The expected term of options granted under the Plans, all of which qualify as plain vanilla, is based on the average of the contractual term (10 years) and the vesting period (generally, 48 months). For non-employee options, the expected term is the contractual term. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option. The assumptions used principally in determining the fair value of options granted were as follows:

| | March 31, 2014 |
|-------------------------|---------------------------|
| Risk-free interest rate | 2.03% |
| Expected dividend yield | 0.00% |
| Expected term | 6.07 |
| Expected volatility | 125.55% |

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A summary of option activity as of March 31, 2014 and changes for the period then ended are presented below:

| Options | Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term in Years | Aggregate Intrinsic Value |
|----------------------------------|------------|---------------------------------|--|---------------------------|
| Outstanding at December 31, 2013 | 8,055,522 | \$ 1.56 | | |
| Granted | 2,650,000 | \$ 2.29 | | |
| Expired | (6,771) | \$ 1.88 | | |
| Forfeited | (214,379) | \$ 1.80 | | |
| Exercised | (52,625) | \$ 1.97 | | |
| Outstanding at March 31, 2014 | 10,431,747 | \$ 1.73 | 7.69 | \$ 3,989,065 |
| Vested at March 31, 2014 | 4,055,415 | \$ 1.03 | 5.08 | \$ 3,645,280 |

The weighted average grant-date fair value of options granted during the three months ended March 31, 2014 was \$2.03 per share. The total fair value of options that vested in three months ended March 31, 2014 was \$0.97. As of March 31, 2014, there was \$8,770,968 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 3.23 years at March 31, 2014.

11. WARRANTS

The following presents information about warrants to purchase Common Stock issued and outstanding at March 31, 2014:

| Year Issued | Classification | Number of Warrants | Exercise Price | Date of Expiration |
|---------------------------------|----------------|--------------------|----------------|----------------------|
| 2010 | Equity | 1,494,603 | \$ 1.40 | 10/26/2017 12/3/2017 |
| 2010 | Equity | 1,318,268 | \$ 1.00 | 9/26/2015 12/3/2015 |
| 2011 | Equity | 16,071 | \$ 1.40 | 6/17/2018 |
| 2011 | Equity | 343,137 | \$ 3.06 | 12/21/2016 |
| 2012 | Equity | 36,145 | \$ 1.66 | 10/5/2019 |
| Total | | 3,208,224 | | |
| Weighted average exercise price | | | \$ 1.42 | |
| Weighted average life in years | | | | 3.37 |

12. DERIVATIVE INSTRUMENTS

Certain warrants issued to investors and the placement agent warrants in the fourth quarter of 2010 had provisions that included anti-dilution protection and, under certain conditions, granted the right to the holder to require the Company to repurchase the warrant. Accordingly through March 2013, these warrants were accounted for as derivative liabilities. The Company used the Black-Scholes option pricing model and assumptions that consider among other factors the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants considered to be derivative instruments. Changes in fair value of the derivative financial instruments are recognized in the Company's consolidated statement of operations as a derivatives gain or loss. The warrant derivative gains (losses) are non-cash income (expenses) and for the three months ended March 31, 2013, a loss of \$10,449,000 were included in other expense, net in the Company's consolidated statements of operations. No such expenses were recorded for the three months ended March 31, 2014.

In the quarter ended March 31, 2013, \$476,000 was reclassified from a derivative warrant liability to additional paid-in capital related to the exercise of the 2010 warrants. In May 2013, the Company called for the redemption of all the outstanding investor warrants issued in 2010 in accordance with the terms of those warrants and as a result, during the quarter ended June 30, 2013, a total of 11,726,343 warrants were exercised, providing cash proceeds of \$15,984,304. There were no derivative instruments subsequent to June 30, 2013.

13. INSURANCE CLAIM

During the three months ended March 31, 2013, the Company received insurance proceeds of approximately \$1,100,000 from the settlement of a business interruption claim that covered the disruption of the Company's operations at its facility in Cambridge, MA due to water damage that occurred in November 2012. The insurance settlement reimbursed the Company for costs incurred as a result of the disruption and was recorded as a reduction of research and development expense in the Company's consolidated statements of operations for the three months ending March 31, 2013.

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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, 2013 (the 2013 Annual Report). The management's discussion and analysis contains forward-looking statements within the meaning of the safe harbor provisions under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements include statements made regarding our commercialization strategy, future operations, capital requirements and other statements on our strategy, financial position, plans, 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 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 2013 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 develop novel biomaterial technologies for the treatment of spinal cord injuries and hydrogels for therapeutics delivery. Our proprietary technologies incorporate intellectual property that is licensed under our exclusive, world-wide license from Children's Medical Center Corporation (CMCC) and the Massachusetts Institute of Technology (MIT), as well as intellectual property that has been developed internally in collaboration with our advisors and partners. At March 31, 2014, we were considered a development stage enterprise and will continue to be so until we commence commercial operations. A development stage enterprise is one in which planned principal operations have not commenced or, if its operations have commenced, there has been no significant revenue from operations. Development stage companies report cumulative costs from the date of inception of the enterprise.

Our development stage started on November 28, 2005 and continued through March 31, 2014. As of March 31, 2014, we have experienced total net losses since inception of approximately \$87,012,000. As a development stage enterprise, we expect to incur substantial operating losses in the future and are therefore dependent upon external financing, such as from equity and debt offerings, to finance our operations. Before we can derive revenue or cash inflows from the commercialization of any of our products, we will need to conduct clinical studies and obtain regulatory approval to commercialize our products.

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

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

Recent Events

Pilot Clinical Study Update

Our scaffold product is currently being studied in an early feasibility, five subject pilot study under our approved Investigational Device Exemption application (IDE) and such study will be conducted in as many as six sites across the United States. In April 2014, we shipped our scaffold product to our initial clinical site at The University of Arizona Medical Center in Tucson, Arizona. We have received Institutional Review Board, or IRB, approval from two additional clinical study sites and expect that these two sites will be open to enroll subjects in the second quarter of 2014.

Under the conditions of the FDA's approval of an IDE, our pilot clinical study is a staggered trial such that each patient that meets the study criteria will be followed for three months prior to requesting approval to enroll the next patient. In addition, following implantation of our scaffold product, we will monitor the patient at 24, 48 and 72 hours, one week, at discharge, and at one, three, six and 12 months.

Even if our pilot clinical studies are successful and we are able to obtain FDA approval of a Humanitarian Use Device (HUD) for our scaffold product, because the scaffold product is a 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. For major markets outside the United States, we would be required to seek regulatory approvals in those markets after the clinical trials are conducted in the United States.

May 2014 Offering

On May 9, 2014, we closed an underwritten public offering of an aggregate of 14,001,250 shares of common stock and warrants to purchase an aggregate of 7,000,625 shares of common stock, at a price to the public of \$1.15 per share of common stock and \$0.00001 per warrant. The underwriting discount was 7% of the public offering price of the shares, or \$0.0805 per share and 0.0000007 per warrant.

The warrants have an initial per share exercise price of \$1.4375 (125% of public offering price of the common stock) and will expire on May 9, 2019. The warrants are immediately exercisable, at the option of each holder, in whole or in part, in cash (except in the case of a cashless exercise as discussed below). The exercise price and number of shares of common stock issuable upon exercise of the warrants will be subject to adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, reorganization or similar transaction, among other events as described in the warrants. In addition, the exercise price and the number of shares issuable upon exercise are subject to adjustment in the event of sales of our common stock at a price per share less than the exercise price of the warrants then in effect (or securities convertible or

exercisable into common stock at a conversion or exercise price less than the exercise price then in effect) and also upon any distributions of assets, including cash, stock or other property to our stockholders. 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 net proceeds, after deducting underwriting discounts and offering expenses, were approximately \$14.6 million. We expect this amount to be sufficient to meet our operating and capital requirements until November 2015, and intend to use the proceeds for general corporate purposes, including for the research, development and pre-clinical studies for our product candidates, the completion of our scaffold pilot clinical study, and for working capital.

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

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the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

On an ongoing basis, we evaluate our estimates and judgments for all assets and liabilities, including those related to stock-based compensation expense and the fair value determined for stock purchase warrants classified as derivative liabilities. We base our estimates and judgments on historical experience, current economic and industry conditions and on various other factors that are believed to be reasonable under the circumstances. This forms the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. There have been no changes in our critical accounting policies and estimates from our 2013 Annual Report.

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

Results of Operations

Comparison of the Three Months Ended March 31, 2014 and 2013

Research and Development Expenses

Research and development expenses consisted primarily of payments to contract research and development companies and payroll. Research and development expenses increased by approximately \$2,029,000 to approximately \$3,242,000 for the three months ended March 31, 2014, as compared to approximately \$1,213,000 for the three months ended March 31, 2013. The increase in expenses for the three months ended March 31, 2014 was primarily attributable to our receipt of \$1,100,000 in proceeds from a settlement of a business interruption claim, which was recorded as a reduction of research and development expenses for the three months ended March 31, 2013; \$334,000 in increased compensation costs due to both additional staffing costs and pay raises; an increase in prototype costs of \$350,000; and an increase in stock compensation expense of \$218,000.

General and Administrative Expenses

General and administrative expenses consisted primarily of payroll, rent and professional services. General and administrative expenses increased by approximately \$191,000 to approximately \$1,829,000 for the three months ended March 31, 2014, as compared to approximately \$1,638,000 for the three months ended March 31, 2013. The increase in expenses for the three months ended March 31, 2014 was primarily attributable to \$70,000 in increased legal costs; \$70,000 in increased recruiting costs; \$23,000 in increased payroll expenses; \$31,000 in insurance expenses; and an increase of stock compensation expense of \$185,000, partially offset these increases were by a reductions in travel & entertainment of \$120,000, a reduction in donations of \$46,000, and a reduction in other various expenses of \$22,000.

Interest Expense

Interest expense increased by \$4,000 to \$33,000 for the three months ended March 31, 2014, as compared to \$29,000 for the three months ended March 31, 2013. The increase in interest expense for the three months ended March 31, 2014 was mainly due to an increase in borrowings under our loan payable.

Liquidity and Capital Resources

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

Since inception, we have experienced negative cash flows from operations. We have financed our operations primarily through sales of equity-related securities. At March 31, 2014, our deficit accumulated during the development stage was \$87,012,000.

At March 31, 2014, we had total current assets of \$10,662,000 and current liabilities of \$2,014,000, resulting in working capital of \$8,648,000. At March 31, 2014, we had total assets of \$12,996,000 and total liabilities of \$3,934,000, resulting in stockholders' equity of \$9,062,000.

Net cash used in operating activities for the three months ended March 31, 2014 was approximately \$4,194,000, as compared to net cash used in operating activities of approximately \$2,669,000 for the three months ended March 31, 2013. The change in net cash provided by operating activities for the three months ended March 31, 2014 as compared to the same period in the prior year was primarily due to a \$8,223 decrease in our net operating loss of \$5,103,000 as compared to \$13,326 offset by an increase in cash flows from operations for \$10,449 non-cash derivative loss for the three months ended March 31, 2013. There were no derivatives for the

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three months ended March 31, 2014. Significant commitments that will require the use of cash in operating activities in future periods include our obligations under operating leases. Our gross committed lease obligations amount to approximately \$5,761,000. Total commitments due for the remainder of fiscal 2014 under operating leases are approximately \$905,000.

Net cash used in investing activities for the three months ended March 31, 2014 totaled approximately \$35,000 for purchases of capital equipment, as compared to net cash used in investing activities of \$410,000, also for purchases of capital equipment, for the three months ended March 31, 2013.

Net cash provided by financing activities was approximately \$95,000 for the three months ended March 31, 2014, as compared to net cash provided by financing activities of approximately \$555,000 for the three months ended March 31, 2013. The change in net cash provided by financing activities for the three months ended March 31, 2014 as compared to the same period in the prior year was primarily due to the receipt of \$116,000 from the exercise of stock options and warrants, as compared to \$341, respectively, as well as loan payable proceeds of \$222 for the three months ended March 31, 2013.

At March 31, 2014, we had cash of approximately \$9,846,000. On May 9, 2014, we completed an underwritten public offering of an aggregate of 14,001,250 shares of common stock and warrants to purchase an aggregate of 7,000,625 shares of common stock, at a price to the public of \$1.15 per share of common stock and \$0.00001 per warrant. The net proceeds, after deducting underwriting discounts and offering expenses, were approximately \$14.6 million. We expect this amount to be sufficient to meet our operating and capital requirements until November 2015, and intend to use the proceeds for general corporate purposes, including for the research, development and pre-clinical studies for our product candidates, the completion of our scaffold pilot clinical study, and for working capital.

However, we have incurred significant operating losses and negative cash flows since inception. We have not achieved profitability and may not be able to realize sufficient revenue to achieve or sustain profitability in the future. We do not expect to be profitable in the next several years, but rather expect to incur additional operating losses. We have limited liquidity and capital resources and must obtain significant additional capital resources in order to sustain our product development efforts, for acquisition of technologies and intellectual property rights, for preclinical and clinical testing of our anticipated products, for pursuit of regulatory approvals, for acquisition of capital equipment, laboratory and office facilities, for establishment of production capabilities, and for selling, general and administrative expenses and other working capital requirements. We have, in the past, successfully completed financings, but, due to market conditions and other factors, including our development stage and our ability to continue as a going concern, we may be unable to raise the required capital in the future.

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

The source, timing and availability of any future financing will depend principally upon market conditions, interest rates and, more specifically, on our progress in our exploratory, preclinical and future clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or 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 have no off-balance sheet arrangements, including unrecorded derivative instruments that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

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Item 4. Controls and Procedures.

Disclosure Controls and Procedures

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

Internal Control over Financial Reporting

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

PART II OTHER INFORMATION

Item 1. Legal Proceedings.

In November 2013, we filed a lawsuit against Francis Reynolds, our former Chairman, Chief Executive Officer and Chief Financial Officer, in Middlesex Superior Court, Middlesex County, Massachusetts (InVivo Therapeutics Holdings Corp. v. Reynolds, Civil Action No. 13-5004). The complaint alleges breaches of fiduciary duties, breach of contract, conversion, misappropriation of corporate assets, unjust enrichment, corporate waste, and seeks money damages and an accounting. The lawsuit involves approximately \$500,000 worth of personal and/or exorbitant expenses that the Company alleges Mr. Reynolds inappropriately caused us to pay while he was serving as our Chief Executive Officer, Chief Financial Officer, President and Chairman of our Board of Directors. On December 6, 2013, Mr. Reynolds answered the complaint, and filed counterclaims against us and our Board of Directors. The counterclaims allege two counts of breach of contract, two counts of breach of the covenant of good faith and fair-dealing, and tortious interference with a contract, and seek monetary damages and a declaratory judgment. The counterclaims involve Mr. Reynolds's allegations that we and 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, we, along with the directors named in the counterclaims, filed our answer. The parties are currently conducting pre-trial discovery. No judgments or rulings are pending at this early stage. We do not believe that the pending actions will materially impact the financial condition of our Company.

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

Item 1A. Risk Factors.

Risks Relating to Our Business

We have a limited operating history and it is difficult to predict our future growth and operating results.

We have a limited operating history and limited operations and assets. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties encountered by companies in the early stage of development, including unforeseen capital requirements and technical problems, delays in obtaining regulatory approvals and failure of market acceptance. As a development stage company, our development timelines have been and may continue to be subject to adjustments that could negatively affect our cash flow and ability to develop or bring products to market, if at all. Predicting our future operating and other results is extremely difficult, if not impossible.

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We have not generated any revenues to date and have a history of losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

We have not generated any revenue to date and, through December 31, 2013, have incurred net losses of \$81,909,055 since inception. It can be expected that we will continue to incur significant operating expenses and continue to experience losses in the foreseeable future. As a result, we cannot predict when, if ever, we might achieve profitability and cannot be certain that we will be able to sustain profitability, if achieved.

There is substantial doubt about our ability to continue as a going concern, which will affect our ability to obtain future financing and may require us to curtail our operations.

Our financial statements as of December 31, 2013 were prepared under the assumption that we will continue as a going concern. The independent registered public accounting firm that audited our 2013 financial statements, in their report, included an explanatory paragraph referring to our recurring losses since inception and expressing substantial doubt in our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. At December 31, 2013, we had cash and cash equivalents of \$13,980,321. Our ability to continue as a going concern depends on our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue.

We will need substantial additional funding to develop our products and for our future operations. If we are unable to obtain the funds necessary to do so, we may be required to delay, scale back or eliminate our product development or may be unable to continue our business.

The development and approval to market and sell our products will require a commitment of substantial funds, in excess of our current capital resources. Before we can market or sell any of our products, we will need to conduct costly and time-consuming research, which includes preclinical and clinical testing and regulatory approvals. We anticipate the amount of operating funds that we use will continue to increase along with our operating expenses over at least the next several years as we plan to bring our products to market. On May 9, 2014, we completed an underwritten public offering of an aggregate of 14,001,250 shares of common stock and warrants to purchase an aggregate of 7,000,625 shares of common stock, at a price to the public of \$1.15 per share of common stock and \$0.00001 per warrant. The net proceeds, after deducting underwriting discounts and offering expenses, were approximately \$14.6 million. We expect this amount to be sufficient to meet our operating and capital requirements until November 2015, and intend to use the proceeds for general corporate purposes, including for the research, development and pre-clinical studies for our product candidates, the completion of our scaffold pilot clinical study, and for working capital. However, we will still need to raise substantial capital to develop our products and fund future operations. We cannot be certain that additional financing will be available on acceptable terms, or at all. If we are not successful in raising additional capital, we may not be able to continue as a going concern and we may have to curtail or cease our operations. To the extent we raise additional capital through the sale of equity securities, the ownership position of our existing stockholders could be substantially diluted. If additional funds are raised through the issuance of preferred stock or debt securities, these securities are likely to have rights, preferences and privileges senior to our common stock. Fluctuating interest rates could also increase the costs of any debt financing we may obtain.

Our ability to operate our business as planned could be impacted if an event of default occurs under our promissory note with the Massachusetts Development Finance Agency, or MassDev.

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At December 31, 2013, the principal amount outstanding under the note to MassDev was \$1,920,000. The note was issued in 2012 and advances under the note were primarily used to purchase capital equipment. The annual interest rate on the note is fixed at 6.5% with interest payments only through April 30, 2015, and thereafter equal monthly interest and principal payments until final maturity on October 5, 2019. The note includes events of default, which if not cured or waived, could result in MassDev accelerating the maturity of our debt. Events of default under the note include a default under our lease agreement, if we move operations outside of Massachusetts, and if we fail to maintain at least \$300,000 in cash or marketable securities at all times while amounts are outstanding under the note. In addition, the note is secured by a security interest in substantially all of our assets, and therefore, if we are unable to repay the note, MassDev could foreclose on these assets.

Our products are in an early stage of development and will represent new and rapidly evolving technologies. If we are unable to commercialize our products or experience significant delays in doing so, our business will be materially harmed and we may have to curtail or cease our operations.

Our proprietary spinal cord injury treatment technology depends on new, rapidly evolving technologies and on the marketability and profitability of our products. Approval by applicable regulatory agencies and commercialization of our spinal cord injury treatment technology could fail for a variety of reasons, both within and outside of our control, including the possibility that our products may be ineffective, unsafe or associated with unacceptable side effects, too expensive to develop, manufacture or market, or other parties may

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hold or acquire proprietary rights that could prevent us or our potential collaborators from developing or marketing our products. Furthermore, because there are no approved treatments for spinal cord injuries, the regulatory requirements governing this type of product may be more rigorous or less clearly established than for other analogous products. If we are unable to obtain the required regulatory approvals of our products and subsequently commercialize them, our business will be materially harmed, and we may have to curtail or cease our operations.

If we cannot protect, maintain and, if necessary, enforce our intellectual property rights, our ability to develop and commercialize products will be adversely impacted.

Our success in large part depends on our ability to protect and maintain the proprietary nature of our technology. We and our licensors must prosecute and maintain existing patents and obtain new patents. Some of our proprietary information may not be patentable, and there can be no assurance that others will not utilize similar or superior solutions to compete with us. We cannot guarantee that we will develop proprietary products that are patentable, and that if issued, any patent will give a competitive advantage or that such patent will not be challenged by third parties. The process of obtaining patents can be time consuming with no certainty of success, as a patent may not issue or may not have sufficient scope or strength to protect the intellectual property it was intended to protect. We cannot assure you that our means of protecting our proprietary rights will suffice or that others will not independently develop competitive technology, or design around patents or other intellectual property rights issued to us. Even if a patent is issued, it does not guarantee that it is valid or enforceable. Any patents that we or our licensors have obtained or obtain in the future may be challenged, invalidated or unenforceable. If necessary, we may initiate actions to protect our intellectual property, which can be costly and time consuming.

If third parties successfully claim that we infringe their intellectual property rights, our ability to continue to develop and commercialize products could be delayed or prevented.

Third parties may claim that we or our licensors are infringing on or misappropriating their proprietary information. Other organizations are engaged in research and product development efforts that may overlap with our products. Such third parties may currently have, or may obtain in the future, legally blocking proprietary rights, including patent rights, in one or more products or methods under development or consideration by us. These rights may prevent us from commercializing products, or may require us to obtain a license from the organizations to use the technology. We may not be able to obtain any such licenses that may be required on reasonable financial terms, if at all, and cannot be sure that the patents underlying any such licenses will be valid or enforceable. There may be rights that we are not aware of, including applications that have been filed but not published that, when issued, could be asserted against us. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research and development of the product that is the subject of the suit. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our trade secrets or other confidential information could be compromised by disclosure during this type of litigation.

We license the technology underlying our scaffold product from CMCC and MIT. If a dispute with CMCC or MIT arises or if we fail to comply with the financial and other terms of the license, we could lose our rights to this license, which would result in a material harm to our business.

We license certain technology underlying our scaffold product under a patent license from CMCC and MIT. This license agreement imposes certain payment, milestone achievement, reporting, confidentiality and other obligations on us. In the event that we were to breach any of the obligations and fail to cure them, CMCC would have the right to terminate this license agreement upon notice. In addition, CMCC has the right to terminate this license upon the bankruptcy or receivership of the Company. The termination of this license could have a material adverse

effect on our business, to the extent our current scaffold was developed from these licensed patents and related intellectual property. If any dispute arises with respect to our arrangement with CMCC or MIT, such dispute may disrupt our operations and would likely have a material and adverse impact on us if resolved in a manner that is unfavorable to us.

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We will require FDA approval before we can sell any of our products in the United States and approval of similar regulatory authorities in countries outside the United States before we can sell our products in such countries. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our products if such approval is denied or delayed.

The development, manufacture and marketing of our products are subject to government regulation in the United States and other countries. In the United States and most foreign countries, we must complete rigorous preclinical testing and extensive human clinical trials that demonstrate the safety and efficacy of a product in order to apply for regulatory approval to market the product.

Our biopolymer scaffold product is expected to be regulated as a Class III medical device by the FDA. The FDA-approval process is expensive and can take many years to complete, and we may not be able to demonstrate the safety and efficacy of our products to the satisfaction of the FDA or the regulatory authorities of other countries. Regulatory agencies may require us to delay, restrict or discontinue clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Regulatory authorities may also require additional testing, and we may be required to demonstrate that our proposed products represent an improved form of treatment over existing therapies, which we may be unable to do without conducting further clinical studies. Delays in regulatory approval can be extremely costly in terms of losing any potential marketing advantage of being early to market. Moreover, if the FDA grants regulatory approval of a product, the approval may be limited to specific indications or limited with respect to its distribution. Expanded or additional indications for approved devices or drugs may not be approved, which could limit our potential revenues. Foreign regulatory authorities may apply similar limitations or may refuse to grant any approval. Consequently, even if we believe that preclinical and clinical data are sufficient to support regulatory approval for our products, the FDA and foreign regulatory authorities may not ultimately grant approval for commercial sale in any jurisdiction. If our products are not approved, our ability to generate revenues will be limited and our business will be adversely affected.

If our clinical studies are unsuccessful or significantly delayed, our ability to commercialize our scaffold product will be impaired.

Before we can obtain regulatory approval for the sale of our scaffold product, we must complete a pilot and pivotal clinical study. Although we have obtained some results from preclinical testing of our intended products in animals, we may not see positive results when any of our scaffold products undergoes clinical testing in humans. Our preclinical testing to date has been limited in nature and we cannot predict whether more extensive clinical testing will obtain similar results. Even if the results of our clinical studies in humans are promising, our scaffold product may subsequently fail to meet the safety and efficacy standards required to obtain regulatory approvals.

Our pilot clinical study may not be successfully completed or may take longer than anticipated because of any number of factors, including potential delays in the start of the trial, the availability of scaffolds to supply our clinical sites, failure to demonstrate safety and efficacy, unforeseen safety issues, or unforeseen governmental or regulatory delays. Further, regulatory authorities and Institutional Review Boards that must approve and monitor the safety of any clinical study may suspend a clinical study at any time if the patients participating in such study are deemed to be exposed to any unacceptable health risk. Additionally, even if we are able to successfully complete our pilot and pivotal clinical studies, the FDA still may not approve our products.

Pre-clinical studies of our scaffold product may not predict results of human clinical studies, and if the results of our clinical studies indicate that our scaffold product is not safe or effective for human use, our business will suffer.

Pre-clinical studies of our scaffold product in animals may not accurately predict the result of human clinical studies of the scaffold product. The scaffold product may be found not to be safe or effective as a potential treatment for spinal cord injury when used in our human clinical study.

If the results of our current and any future clinical studies indicate that our scaffold product is not safe or effective for human use, our business will suffer. Unfavorable results from clinical studies could result in delays, modifications or abandonment of future clinical studies. Negative or inconclusive results or adverse medical events during a clinical study could cause a clinical study to be delayed, repeated, modified or terminated.

The risks and uncertainties inherent in conducting our clinical study could delay or prevent the development and eventual commercialization of our scaffold product, which could have a material adverse effect on our business, results of operations and financial condition.

There are a number of risks and uncertainties associated with conducting clinical studies. Our clinical study will be conducted with patients having severe injury and, as a result, during the course of treatment these patients can die or suffer adverse medical effects for reasons that may not be related to the scaffold product, but which nevertheless affect the clinical study results. In addition, side effects experienced by the patients may cause delay of the study. Moreover, our clinical study may not demonstrate sufficient safety and efficacy to obtain approval from the FDA for additional studies. The FDA may not agree with our assessment of the clinical data or they may interpret it differently. Failure can occur at any time during the clinical study process and the results from early clinical

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studies may not be predictive of results obtained in later and larger clinical studies. Later clinical studies of our scaffold product, if approved, may fail to show the desired safety or efficacy despite having progressed successfully through earlier clinical studies.

The completion of the pilot clinical study for our scaffold product may be delayed or halted for the reasons noted above in addition to many other reasons, including delays in patient enrollment, and variability in the number and types of patients available for the clinical study, regulators or institutional review boards may not allow us to commence or continue a clinical study, or poor effectiveness of the scaffold product during the clinical study. Any failure or delay in completing clinical studies for our scaffold product would prevent or delay the commercialization of our scaffold product, which could have a material adverse effect on our business, results of operations and financial condition.

Approval to promote, manufacture and sell our products, if granted, is subject to continuing review, which may require the expenditure of substantial resources and subject us to continuing uncertainty.

Even if a product gains regulatory approval, such approval is limited to the patient population studied in our clinical trials, and the product and the manufacture of the product will be subject to continuing regulatory review, including adverse event reporting requirements and the FDA's general prohibition against promoting products for unapproved uses. Failure to comply with any post-approval requirements can, among other things, result in warning letters, product seizures, recalls, substantial fines, injunctions, suspensions or revocations of marketing licenses, operating restrictions and criminal prosecutions. Any of these enforcement actions, any unanticipated changes in existing regulatory requirements or the adoption of new requirements, or any safety issues that arise with any approved products, could adversely affect our ability to market products and generate revenues and thus adversely affect our ability to continue our business.

We also may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or its manufacture are subsequently discovered and we cannot provide assurance that newly discovered or developed safety issues will not arise following any regulatory approval.

We will face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The biotechnology industry in general is subject to intense competition and rapid and significant technological change. We have many potential competitors, including major drug companies, specialized biotechnology firms, academic institutions, government agencies and private and public research institutions. Many of these competitors have significantly greater financial and technical resources than us, and superior experience and expertise in research and development, preclinical testing, designing and implementing clinical trials, regulatory processes and approvals, production and manufacturing, and sales and marketing of approved products.

Large and established companies compete in the biotech market. In particular, these companies have greater experience and expertise in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale and marketing approved products. Smaller or early-stage companies and research institutions may also prove to be significant competitors, particularly through collaborative arrangements with large and established biotech or other companies. We will also face competition from these parties in recruiting and retaining qualified scientific and management

personnel, establishing clinical trial sites and registering subjects for clinical trials.

In order to effectively compete, we will have to make substantial investments in development, testing, manufacturing and sales and marketing or partner with one or more established companies. There is no assurance that we will be successful in having our products approved or gaining significant market share for any of our products. Our technologies and products also may be rendered obsolete or noncompetitive as a result of products introduced by our competitors.

We will depend upon strategic relationships to develop, exploit and manufacture our products. If these relationships are not successful, we may not be able to capitalize on the market potential of these products.

The near and long-term viability of our products will depend in part on our ability to successfully establish new strategic collaborations with biotechnology companies, hospitals, insurance companies and government agencies. Establishing strategic collaborations is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of our

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financial, regulatory or intellectual property position. If we fail to establish a sufficient number of collaborations on acceptable terms, we may not be able to commercialize our products or generate sufficient revenue to fund further research and development efforts.

Even if we establish new collaborations, these relationships may never result in the successful development or commercialization of any product candidates for several reasons both within and outside of our control.

We have limited experience manufacturing our scaffold product for clinical-study scale and no experience for commercial scale.

We have manufactured our scaffold product on a small scale, including in such amounts that will be needed for our pilot and pivotal clinical studies. We may encounter unanticipated problems in the scale-up process that will result in delays in the manufacturing of the scaffold product, and therefore delay our clinical studies. We are subject to FDA regulations that require us to manufacture our scaffold products in compliance with the FDA requirements of Design Controls and are subject to inspections by regulatory agencies. Our failure to comply with applicable regulations may result in delays and interruptions to our product supply while we seek to secure another supplier that meets all regulatory requirements. If we are unable to scale up our manufacturing to meet requirements for our clinical studies, we may be required to rely on contract manufacturers. Reliance on third party manufacturers entails risks to which we would not be subject if we manufactured the product ourselves, including the possible breach of the manufacturing agreements by the third parties because of factors beyond our control; and the possibility of termination or nonrenewal of the agreements by the third parties because of our breach of the manufacturing agreement or based on their own business priorities.

There is a limited number of suppliers that can provide materials to us. Any problems encountered by such suppliers may detrimentally impact us.

We may rely on third-party suppliers and vendors for some of the materials used in the manufacture of our products or other of our product candidates. Any significant problem experienced by one of our suppliers could result in a delay or interruption in the supply of materials to us until such supplier resolves the problem or an alternative source of supply is located. Any delay or interruption could negatively affect our operations.

We will rely upon third parties for laboratory testing, animal and human clinical studies which exposes us to increased risk.

We have been and will continue to be dependent on third-party contract research organizations to conduct some of our laboratory testing, animal and human clinical studies. If we are unable to obtain any necessary testing services on acceptable terms, we may not complete our product development efforts in a timely manner. If we rely on third parties for laboratory testing and animal or human studies, we may lose some control over these activities and become too dependent upon these parties. These third parties may not complete testing activities on schedule or when we request. We may not be able to secure and maintain suitable contract research organizations to conduct our laboratory testing and animal or human studies. We are responsible for confirming that each of our clinical trials is conducted in accordance with our approved plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties

need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our product candidates.

If approved, our products will require market acceptance to be successful. Failure to gain market acceptance would impact our revenues and may materially impair our ability to continue our business.

Even if we receive regulatory approvals for the commercial sale of our products, the commercial success of these products will depend on, among other things, their acceptance by physicians, patients, third party payers such as health insurance companies and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. If our product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, both within and outside of our control. If our products do not become widely accepted by physicians, patients, third party payers and other members of the medical community, our business, financial condition and results of operations would be materially and adversely affected.

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Acquisitions of companies, businesses or technologies may substantially dilute our stockholders and increase our operating losses.

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 such acquisition may require assimilation of the operations, products or product candidates and personnel of the acquired business and the training and integration of its employees, and could substantially increase our operating costs, without any offsetting increase in revenue. Acquisitions may not provide the intended technological, scientific or business benefits and could disrupt our operations and divert our limited resources and management's attention from our current operations, which could harm our existing product development efforts. While we may use cash or equity to finance a future acquisition, it is likely we would issue equity securities as a portion or all of the consideration in any acquisition. The issuance of equity securities for an acquisition could be substantially dilutive to our stockholders. Any investment made in, or funds advanced to, a potential acquisition target could also significantly adversely affect our results of operation and could further reduce our limited capital resources. Any acquisition or action taken in anticipation of a potential acquisition or other change in business activities could substantially depress the price of our stock. In addition, our results of operations may suffer because of acquisition-related costs or the post-acquisition costs of funding the development of an acquired technology or product candidates or operation of the acquired business, or due to amortization or impairment costs for acquired goodwill and other intangible assets.

Physicians and hospitals will require training in order to utilize our products and our success depends upon the acceptance and adoption of our products by physicians and hospitals.

Our products have not been utilized in the past for spinal cord injury treatment. As is typical in the case of a new and rapidly evolving technology or medical treatment, demand and market acceptance for recently introduced products and services are subject to a high level of uncertainty and risk. In addition, physicians and hospitals will need to establish training and procedures to utilize and implement our products, if such products are approved by the FDA. There can be no assurance that these parties will adopt our products or that they develop sufficient training and procedures to properly utilize our products.

If we obtain approval for our products, their commercial success will depend in part upon the level of third party reimbursement for the cost of our products to users.

The commercial success of any product will depend, in part, on the extent to which reimbursement for the costs of the products and related treatments will be available from third-party payers such as government health administration authorities, private health insurers, managed care programs, and other organizations. Adequate third-party insurance coverage may not be available for us to establish and maintain price levels that are sufficient for us to continue our business or for realization of an appropriate return on investment in product development.

We are subject to environmental, health and safety laws. Failure to comply with such environmental, health and safety laws could cause us to become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and humans, emissions and wastewater discharges, and the use and disposal of hazardous or potentially hazardous substances used in connection with our research. We also cannot accurately predict the extent of regulations that might result from any future legislative or administrative action. Any of these laws or regulations could cause us to incur additional expense or restrict our operations. Compliance with

environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs.

As is custom in our industry, we will have exposure to claims for product liability. Product liability coverage is expensive and sometimes difficult to obtain. We may not be able to obtain or maintain insurance at a reasonable cost. We currently have product liability insurance, however, there can be no assurance that our existing insurance coverage will extend to our other products, if any, in the future. Any product liability insurance coverage may not be sufficient to satisfy all liabilities resulting from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable items, if at all. Even if a claim is not successful, defending such a claim would be time-consuming and expensive, may damage our reputation in the marketplace, and would likely divert management's attention.

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Our success depends on our ability to retain our management and other key personnel.

We depend on our senior management as well as key scientific and other personnel. In 2013 and 2014, we have had certain changes in management, including the departure or resignation of key members of our senior management. Our future success is dependent on retaining key individuals within our Company to execute our strategic plans. The loss of the services of any of our senior management could harm our business and significantly delay or prevent the achievement of research, development or business objectives. Competition for qualified employees is intense among biotechnology companies, and the loss of qualified employees, or an inability to attract, retain and motivate additional highly skilled employees could hinder our ability to successfully develop marketable products.

Our future success also depends on our ability to identify, attract, hire, train, retain and motivate other highly skilled scientific, technical, marketing, managerial and financial personnel. Although we will seek to hire and retain qualified personnel with experience and abilities commensurate with our needs, there is no assurance that we will succeed despite our collective efforts. The loss of the services of any of our key personnel could hinder our ability to fulfill our business plan and further develop and commercialize our products and services. Competition for personnel is intense, and any failure to attract and retain the necessary technical, marketing, managerial and financial personnel would have a material adverse effect on our business, prospects, financial condition and results of operations.

Risks Related to Investment in Our Securities

Our securities are penny stock and subject to specific rules governing their sale to investors.

The SEC has adopted Rule 15c-9 which establishes the definition of a penny stock, for the purposes relevant to us, as any equity security that has a market price of less than \$5.00 per share or with an exercise price of less than \$5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require that a broker or dealer approve a person's account for transactions in penny stocks; and the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must obtain financial information and investment experience objectives of the person; and make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks. The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form sets forth the basis on which the broker or dealer made the suitability determination; and that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the penny stock rules. This may make it more difficult for our shareholders to sell shares of our common stock.

Our common stock is quoted on the OTCQB, which may limit the liquidity and price of our common stock more than if our common stock was listed on a national securities exchange.

Our common stock is currently quoted on the OTCQB, an inter-dealer automated quotation system for equity securities not listed on a national securities exchange. Quotation of our common stock on the OTCQB may limit the liquidity and price of our common stock more than if our common stock was quoted or listed on a national securities exchange. Some investors may perceive our common stock to be less attractive because it is quoted in the over-the-counter market. In addition, as an OTCQB company, we do not attract the extensive analyst coverage that accompanies companies listed on a national securities exchange. Further, institutional and other investors may have investment guidelines that restrict or prohibit investing in securities traded in the over-the-counter market. In addition, holders of our common stock may face restrictions on the resale of our common stock due to state blue sky laws. These factors may have an adverse impact on the trading and price of our common stock.

The price of our common stock is volatile, which could lead to losses by investors and costly securities litigation.

The trading price of our common stock is volatile and could continue to fluctuate in response to factors such as:

- actual or anticipated variations in our operating results;

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- announcements of developments by us or our competitors;
- the completion and/or results of our clinical trials;
- regulatory actions regarding our products;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- adoption of new accounting standards affecting our industry;
- additions or departures of key personnel;
- introduction of new products by us or our competitors;
- sales of our common stock or other securities in the open market; and
- other events or factors, many of which are beyond our control.

The stock market is subject to significant price and volume fluctuations. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been initiated against such company. Litigation initiated against us, whether or not successful, could result in substantial costs and diversion of our management's attention and resources, which could harm our business and financial condition.

Investors may experience dilution of their ownership interests because of the future issuance of additional shares of our common stock, or securities exercisable or convertible into, or exchangeable for, shares of our common stock.

As of May 9, 2014, there were outstanding warrants to purchase 10,208,849 shares of our common stock, and outstanding options to purchase 10,377,267 shares of our common stock. We expect to issue additional equity awards to compensate employees, consultants and directors, and may issue additional securities to raise capital, to acquire other companies or technologies, to pay for services, or for other corporate purposes. Any such issuances will have the effect of diluting the interest of our current stockholders. The future issuance of any such additional securities may create downward pressure on the trading price of the common stock. There can be no assurance that we will not be required to issue additional shares, warrants or other securities exercisable or convertible into, or exchangeable for, shares of our common stock in the future in conjunction with any capital raising efforts, including at a price (or exercise or conversion prices) below the price at which shares of our common stock are currently quoted on the OTCQB.

Certain of our warrants have price protection features that may require adjustment in the exercise price and number of shares issuable upon exercise of the warrants, which could require us to issue a greater number of shares of common stock upon exercise of the warrants, causing dilution to our stockholders and making it more difficult to raise additional equity capital.

In May 2014, we completed a public offering of our common stock and warrants to purchase shares of common stock. These warrants may require an adjustment in the exercise price and number of shares issuable upon exercise of the warrants if we issue common stock, warrants or other equity securities below the exercise price of these warrants (subject to certain exceptions). While these warrants are outstanding, if we

issue any additional equity securities at a price below the exercise price of these warrants, it would result in a reduction in the exercise price and in certain circumstances an increase in the number of shares issuable upon exercise of these warrants. Any adjustment in these warrants could affect the market price of the common stock, result in additional dilution to our stockholders and make it more difficult to raise additional equity capital while these warrants are outstanding. ***The change in value of our derivative liabilities could have a material effect on our financial results in future periods.***

In May 2014, we completed a public offering of our common stock and warrants to purchase shares of common stock. As a result of certain price protection features of the warrants issued in the offering, the warrants are considered a derivative liability under U.S. generally accepted accounting principles. At each of our financial reporting periods, we will be required to determine the fair value of these warrants and record the fair value adjustments as non-cash unrealized gains or losses. The share price of our common stock represents the primary underlying variable that impacts the value of the derivative instruments, as well as the volatility of our stock price. Due to the volatile nature of our stock price, we expect that we will recognize non-cash gains or losses on these warrants in each reporting period and that the amount of such non-cash gains or losses could be material.

We are in litigation with Francis M. Reynolds, our former Chairman, Chief Executive Officer and Chief Financial Officer. The pending litigation with Mr. Reynolds will consume significant management time and Company resources and could materially negatively affect our financial position and cause our stock price to decline.

In November 2013, we filed a lawsuit against Francis M. Reynolds, our former Chairman, Chief Executive Officer and Chief Financial Officer, in Middlesex Superior Court, Middlesex County, Massachusetts (InVivo Therapeutics Holdings Corp. v. Reynolds, Civil Action No. 13 5004). The complaint alleges breaches of fiduciary duties, breach of contract, conversion, misappropriation of

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corporate assets, unjust enrichment, corporate waste, and seeks money damages and an accounting. In December 2013, Mr. Reynolds answered the complaint and filed counterclaims against us and our Board of Directors alleging breach of contract, breach of the covenant of good faith and fair dealing, and tortious interference with contract, and seeking monetary damages and a declaratory judgment. In January 2014, we and the directors named in the counterclaims filed an answer, and the parties are currently conducting pre-trial discovery. While at this early stage we do not believe that the continuation of the pending actions or the settlement or judicial resolution thereof will materially impact our financial condition, neither the ultimate outcome of the litigation nor the amount and range of potential costs associated with the litigation can be assessed with certainty. Defending this lawsuit will consume significant management time and resources and could, depending on the outcome, materially negatively affect our financial position and cause our stock price to decline.

Our former Chairman, Chief Executive Officer and Chief Financial Officer, Francis M. Reynolds, has nominated himself for election as a Class III director at our 2014 annual meeting of stockholders. Any proxy contest, should Mr. Reynolds engage in a full opposition solicitation campaign, would consume significant management time and resources, and could materially negatively affect our financial position and cause our stock price to decline.

In March 2014, Francis M. Reynolds, our former Chairman, Chief Executive Officer and Chief Financial Officer, nominated himself pursuant to our bylaws as a Class III director-nominee for election at our 2014 annual meeting of stockholders. Mr. Reynolds subsequently indicated his intention to solicit proxies for his election at the 2014 annual meeting, and we anticipate that Mr. Reynolds may engage in a full solicitation campaign in opposition to the election of as a Class III director of expected nominee Mark Perrin, our Chief Executive Officer and current Class III director. Any proxy contest with Mr. Reynolds would consume significant management time and resources, and could materially negatively affect our financial position and cause our stock price to decline. If Mr. Reynolds is elected to our Board of Directors, it could affect the ability of our Board of Directors to function effectively, create perceived uncertainties as to our future direction and may make it more difficult for us to attract and retain qualified personnel and business partners.

Anti-takeover effects of certain provisions of our articles of incorporation and Nevada state law may discourage or prevent a takeover.

Our articles of incorporation divide the board of directors into three classes, with three-year staggered terms. The classified board provision could increase the likelihood that, in the event an outside party acquired a controlling block of our stock, incumbent directors nevertheless would retain their positions for a substantial period, which may have the effect of discouraging, delaying or preventing a change in control. In addition, Nevada has a business combination law, which prohibits certain business combinations between Nevada corporations and interested stockholders for three years after the interested stockholder first becomes an interested stockholder, unless the corporation's board of directors approves the combination in advance. In addition, we may become subject to Nevada's control share laws. A corporation is subject to Nevada's control share law if it has more than 200 stockholders, at least 100 of whom are stockholders of record and residents of Nevada, and if the corporation does business in Nevada, including through an affiliated corporation. This control share law may have the effect of discouraging corporate takeovers. Currently, we have less than 100 stockholders of record who are residents of Nevada, and are therefore not subject to the control share laws.

The provisions of our articles of incorporation and Nevada's business combination and control share laws make it more difficult for a third party to acquire us and make a takeover more difficult to complete, even if such a transaction were in our stockholders' interest or might result in a premium over the market price for our common stock.

We have never declared any cash dividends and do not expect to declare any in the near future.

We have never paid cash dividends on our common stock. It is currently anticipated that we will retain earnings, if any, for use in the development of our business and we do not anticipate paying any cash dividends in the foreseeable future.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

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Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

We have not yet announced its meeting date for our 2014 annual meeting of stockholders (the 2014 Annual Meeting). Because we expect that the 2014 Annual Meeting date will represent a change of more than thirty days from the anniversary of our 2013 annual meeting of stockholders held on May 23, 2013, the deadline for the receipt of stockholder proposals for the 2014 Annual Meeting will change. At such time the 2014 Annual Meeting date is set, we will publicly announce such date and deadlines for the receipt of stockholder proposals.

Item 6. Exhibits.

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

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: May 12, 2014

INVIVO THERAPEUTICS HOLDINGS CORP.

By: */s/ STEVEN F. MCALLISTER*

Name: Steven F. McAllister

Title: *Interim Chief Financial Officer
(Principal Financial Officer)*

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EXHIBIT INDEX

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

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