INVIVO THERAPEUTICS HOLDINGS CORP.
Form 10-Q
August 08, 2017
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2017

or

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

For the transition period from to .

Commission File Number: 001-37350

InVivo Therapeutics Holdings Corp.

(Exact name of registrant as specified in its charter)

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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 August 1, 2017, 32,184,943 shares of the registrant's common stock, $0.00001 par value, were issued and outstanding.

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INVIVO THERAPEUTICS HOLDINGS CORP.

Quarterly Report on Form 10-Q for the Quarter Ended June 30, 2017

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PART I — FINANCIAL INFORMATION

Item 1.Financial Statements.

InVivo Therapeutics Holdings Corp.

Consolidated Balance Sheets

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

(Unaudited)

	As of June 30, 2017	December 31, 2016
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 14,322	$ 21,464
Restricted cash	361	361
Marketable securities	7,525	11,577
Prepaid expenses and other current assets	657	451
Total current assets	22,865	33,853
Property, equipment and leasehold improvements, net	305	510
Other assets	409	421
Total assets	$ 23,579	$ 34,784
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 878	$ 1,011
Loan payable, current portion	437	423
Derivative warrant liability	519	1,314
Deferred rent, current portion	154	141
Accrued expenses	1,893	1,959
Total current liabilities	3,881	4,848
Loan payable, net of current portion	630	852
Deferred rent, net of current portion	54	135
Other liabilities	45	—
Total liabilities	4,610	5,835
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, $0.00001 par value, authorized 100,000,000 shares; 32,175,179 shares issued and outstanding at June 30, 2017; 32,044,087 shares issued and outstanding at December 31, 2016	1	1

Accumulated other comprehensive loss	(1)	—
Additional paid-in capital	188,862	185,955
Accumulated deficit	(169,893)	(157,007)
Total stockholders' equity	18,969	28,949
Total liabilities and stockholders' equity	$ 23,579	$ 34,784

See notes to the unaudited consolidated financial statements.

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InVivo Therapeutics Holdings Corp.

Consolidated Statements of Operations and Comprehensive Loss

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

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	$ 3,211	$ 2,795	$ 6,595	$ 5,364
General and administrative	3,715	2,991	7,000	5,990
Total operating expenses	6,926	5,786	13,595	11,354
Operating loss	(6,926)	(5,786)	(13,595)	(11,354)
Other income (expense):				
Interest income	52	36	109	91
Interest expense	(20)	(29)	(40)	(92)
Derivatives gain (loss)	554	595	795	(452)
Other income (expense), net	586	602	864	(453)
Net loss	$ (6,340)	$ (5,184)	$ (12,731)	$ (11,807)
Net loss per share, basic and diluted	$ (0.20)	$ (0.16)	$ (0.40)	$ (0.39)
Weighted average number of common shares outstanding, basic and diluted	32,185,607	31,907,747	32,115,238	30,039,677
Other comprehensive loss:				
Net loss	(6,340)	(5,184)	(12,731)	(11,807)
Other comprehensive loss:				
Unrealized gain (loss) on marketable securities	1	—	(1)	—
Comprehensive loss	$ (6,339)	$ (5,184)	(12,732)	$ (11,807)

See notes to the unaudited consolidated financial statements.

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InVivo Therapeutics Holdings Corp.

Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Six Months Ended June 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	$ (12,731)	$ (11,807)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	264	284
Derivatives (gain) loss	(795)	452
Common stock issued to 401(k) plan	113	109
Share-based compensation expense	2,583	2,396
Non-cash investment (income) expense, net	8	100
Changes in operating assets and liabilities:		
Prepaid expenses	(206)	(498)
Other assets	7	4
Accounts payable	(133)	38
Accrued expenses and other liabilities	(89)	740
Net cash used in operating activities	(10,979)	(8,182)
Cash flows from investing activities:		
Purchases of marketable securities	(8,256)	(6,165)
Sales of marketable securities	12,300	5,860
Purchases of property and equipment	(54)	(73)
Net cash (used in) provided by investing activities	3,990	(378)
Cash flows from financing activities:		
Proceeds from exercise of stock options	26	36
Proceeds from issuance of stock under ESPP	29	43
Repayment of loan payable	(208)	(194)
Proceeds from issuance of common stock and warrants	—	29,905
Net cash (used in) provided by financing activities	(153)	29,790
Increase (decrease) in cash and cash equivalents	(7,142)	21,230
Cash and cash equivalents at beginning of period	21,464	14,920
Cash and cash equivalents at end of period	$ 14,322	$ 36,150
Supplemental disclosure of cash flow information and non-cash transactions:		
Cash paid for interest	$ 40	$ 54

See notes to the unaudited consolidated financial statements.

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InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements for the Quarter Ended June 30, 2017 (Unaudited)

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

Business

InVivo Therapeutics Holdings Corp. was incorporated on April 2, 2003 under the name of Design Source, Inc., and on October 26, 2010 acquired the business of InVivo Therapeutics Corporation, which was incorporated on November 28, 2005, and continued the existing business operations of InVivo Therapeutics Corporation as a wholly-owned subsidiary of InVivo Therapeutics Holdings Corp. Unless otherwise noted herein, the “Company” refers to InVivo Therapeutics Holdings Corp. and its wholly-owned subsidiary on a consolidated basis. The Company is a research and clinical-stage biomaterials and biotechnology company with a focus on the treatment of spinal cord injuries. Its proprietary technologies incorporate intellectual property licensed under the Company’s exclusive, worldwide license from Boston Children’s Hospital and the Massachusetts Institute of Technology, as well as intellectual property that has been developed internally in collaboration with its advisors and partners.

Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets, and raising capital. The Company has historically financed its operations primarily through the sale of equity-related securities. At June 30, 2017, the Company had cash, cash equivalents, and marketable securities of $21.8 million. The Company has not achieved profitability and may not be able to realize sufficient revenue to achieve or sustain profitability in the future. The Company does not expect to be profitable in the next several years, but rather expects to incur additional operating losses. The Company has limited liquidity and capital resources and must obtain significant additional capital resources in order to sustain its product development efforts, for acquisition of technologies and intellectual property rights, for preclinical and clinical testing of its anticipated products, for pursuit of regulatory approvals, for acquisition of capital equipment, laboratory and office facilities, for establishment of production capabilities, for selling, general, and administrative expenses, and for other working capital requirements. The Company expects that it will need additional capital to fund its operations, which it may raise through a combination of equity offerings, debt financings, other third party funding, marketing and distribution arrangements, and other collaborations, strategic alliances, and licensing arrangements.

The Company’s financial statements as of June 30, 2017 were prepared under the assumption that the Company will continue as a going concern. Given the Company’s development plans, it estimates cash resources will be sufficient to fund its operations into the beginning of the second quarter of 2018. This estimate is based on assumptions that may prove to be wrong; expenses could prove to be significantly higher, leading to a more rapid consumption of the Company’s existing resources. Based on the forecast, management determined that there is substantial doubt regarding

the Company's ability to continue as a going concern.

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, 2016 included in the Company's Annual Report on Form 10-K as filed with the United States Securities and Exchange Commission ("SEC") on March 10, 2017. The unaudited consolidated financial statements reflect all adjustments, consisting only of normal recurring adjustments, which are, in the opinion of management, necessary for a fair presentation of the Company's financial position as of June 30, 2017 and its results of operations and cash flows for the interim period presented, and are not necessarily indicative of results for subsequent interim periods or for the full year. The interim financial statements do not include all of the information and footnotes required by GAAP for complete financial statements, as allowed by the relevant SEC rules and regulations; however, the Company believes that its disclosures are adequate to ensure that the information presented is not misleading.

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Reclassifications

Certain amounts in the prior period financial statements have been reclassified to conform to the current period presentation. Cash activities related to the purchase and sale of marketable securities have been reflected within investing activities in the statement of cash flows. The unrealized gains or losses related to these marketable securities are immaterial for the prior period presented.

Recently Issued Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Accounting ("ASU 2016-09") to require changes to several areas of employee share-based payment accounting in an effort to simplify share-based reporting. The update revises requirements in the following areas: minimum statutory withholding, accounting for income taxes, forfeitures, and intrinsic value accounting for private entities. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016, including interim reporting periods within each annual reporting period. The Company adopted this standard on January 1, 2017. Prior to adoption, the Company recognized share-based compensation, net of estimated forfeitures, over the vesting period of the grant. Upon adoption of ASU 2016-09, the Company elected to change its accounting policy to recognize forfeitures as they occur. The Company continues to recognize share-based compensation over the vesting period of the grant. The new forfeiture policy election was adopted using a modified retrospective approach with a cumulative effect adjustment of $155,000 recorded to accumulated deficit on the balance sheet as of January 1, 2017. Prior to January 1, 2017, the Company recognized the excess tax benefits of stock-based compensation expense as additional paid-in capital and tax deficiencies of stock-based compensation expense in the income tax provision or as additional paid-in capital to the extent that there were sufficient recognized excess tax benefits previously recognized. Previously, the excess tax benefits reduced taxes payable prior to being recognized as an increase in additional paid-in capital, and therefore the Company had not recognized certain deferred tax assets that could be attributed to tax deductions. As a result of the adoption, the deferred tax assets associated with certain net operating losses increased, which was offset by a corresponding increase in the valuation allowance and therefore the adoption of the tax-related guidance in this standard did not impact our consolidated financial statements for the period ended June 30, 2017.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The guidance in this ASU supersedes the leasing guidance in Topic 840, Leases. Under the new guidance, lessees are required to recognize lease assets and lease liabilities on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance leases or operating leases, with classification affecting the pattern of expense recognition in the statement of operations. The new standard is effective for annual reporting periods beginning after December 15, 2018, including interim reporting periods within each annual reporting period. The Company is currently evaluating the impact of the adoption of this ASU on the financial statements.

In August 2016, the FASB issued ASU No. 2016-15, Classification of Certain Cash Receipts and Cash Payments ("ASU 2016-15") to address how certain cash receipts and cash payments are presented and classified in the statement of cash flows in an effort to reduce existing diversity in practice. The update includes eight specific cash flow issues and provides guidance on the appropriate cash flow presentation for each. ASU 2016-15 is effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within each annual reporting period. The Company does not expect the adoption of this guidance to have a material impact on the financial statements.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash to clarify how entities should present restricted cash and restricted cash equivalents in the statement of cash flows. Under this new update, entities are required to show the changes in the total of cash, cash equivalents, restricted cash, and restricted cash equivalents in the statement of cash flows. This guidance will be applied retrospectively and is effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within each annual reporting period. The Company does not expect the adoption of this guidance to have a material impact on the financial statements.

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In May 2017, the FASB issued ASU No. 2017-09, Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting ("ASU 2017-09") to clarify when to account for a change to the terms or conditions of a share-based payment award as a modification. Under this new guidance, modification accounting is required if the fair value, vesting conditions, or classification of the award changes as a result of the change in terms or conditions. ASU 2017-09 is effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within each annual reporting period. The Company does not expect the adoption of this guidance to have a material impact on the financial statements.

In July 2017, the FASB issued ASU No. 2017-11, Part I. Accounting for Certain Financial Instruments with Down Round Features and Part II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11"). Part I of this guidance applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down round features. Part II of this guidance replaces the indefinite deferrals for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities. ASU 2017-11 is effective for annual reporting periods beginning after December 15, 2018, including interim reporting periods within each annual reporting period. The Company is currently evaluating the impact of the adoption of this ASU on the financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers ("ASU 2014-09") to provide updated guidance on revenue recognition. ASU 2014-09 requires a company to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies may need to use more judgment and make more estimates than under today's guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price, and allocating the transaction price to each separate performance obligation. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which deferred the effective date of ASU 2014-09 by one year. Accordingly, ASU 2014-09 is effective for public business entities for annual reporting periods beginning after December 15, 2017, including interim reporting periods within each annual reporting period. In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross Versus Net), which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients, which relates to disclosures of remaining performance obligations, as well as other amendments to guidance on collectability, non-cash consideration, and the presentation of sales and other similar taxes collected from customers. These standards have the same effective date and transition date of December 15, 2017. Currently, this guidance is not applicable to the Company as the Company does not generate revenue. However, the Company will evaluate the impact of adopting ASU 2014-09 on its consolidated financial statements when the Company begins to generate revenue.

2.CASH AND CASH EQUIVALENTS

As of June 30, 2017, the Company held $14.3 million 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 considers only those investments that are highly

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liquid, readily convertible to cash, and that mature within three months from date of purchase to be cash equivalents.

At June 30, 2017 and December 31, 2016, cash equivalents were comprised of money market funds and other short-term investments.

Cash and cash equivalents consisted of the following:

(In thousands)	June 30, 2017	December 31, 2016
Cash	$ (87)	$ 111
Money market funds	14,409	21,353
Total cash and cash equivalents	$ 14,322	$ 21,464

3.RESTRICTED CASH

Restricted cash as of June 30, 2017 and December 31, 2016 was $361,000 and included a $50,000 security deposit related to the Company’s credit card account and a $311,000 standby letter of credit in favor of a landlord (see Note 6).

4. MARKETABLE SECURITIES

The Company invests its excess cash in fixed income instruments denominated and payable in U.S. dollars, including money market accounts, commercial paper, asset-backed securities, and corporate obligations, in accordance with the Company’s investment policy that primarily seeks to maintain adequate liquidity and preserve capital.

As of June 30, 2017 and December 31, 2016, the Company’s investment portfolio consisted of marketable securities with an original maturity of greater than 90 days. The Company has designated all investments as available-for-sale and therefore such investments are reported at fair value. Unrealized losses on marketable securities are recorded in accumulated other comprehensive loss, a component of stockholders’ equity, on the balance sheet.

The following table summarizes the Company's investments in marketable securities by category as of June 30, 2017 and December 31, 2016:

(In thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
June 30, 2017				
Current (due within 1 year or less)				
Commercial paper	4,545	—	—	4,545
Corporate obligations	2,231	—	(1)	2,230
Asset backed security	750	—	—	750
Total	$ 7,526	$ —	$ (1)	$ 7,525
December 31, 2016				
Current (due within 1 year or less)				
Commercial paper	4,240	—	—	4,240
Corporate obligations	7,337	—	—	7,337
Total	$ 11,577	$ —	$ —	$ 11,577

5.FAIR VALUE OF ASSETS AND LIABILITIES

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

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

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

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

The Company uses valuation methods and assumptions that consider, among other factors, the fair value of the underlying stock, risk-free interest rate, volatility, expected life, and dividend rates in estimating fair value for the warrants considered to be derivative instruments (see Notes 11 and 12).

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

	At June 30, 2017			
(In thousands)	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	$ 14,409	$ —	$ —	$ 14,409
Marketable securities	—	7,525	—	7,525
Derivative warrant liability	$ —	$ (519)	$ —	$ (519)

	At December 31, 2016			
(In thousands)	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	$ 21,353	$ —	$ —	$ 21,353
Marketable securities	—	11,577	—	11,577
Derivative warrant liability	$ —	$ (1,314)	$ —	$ (1,314)

6.COMMITMENTS AND CONTINGENCIES

Leases

On November 30, 2011, the Company entered into a commercial lease for 26,150 square feet of office, laboratory, and manufacturing space in Cambridge, Massachusetts (as amended on September 17, 2012, the “Cambridge Lease”). The term of the Cambridge Lease is six years and three months, with one five-year extension option. The terms of the Cambridge Lease require a standby letter of credit in the amount of $311,000 (see Note 3).

The Cambridge Lease contains rent holidays and rent escalation clauses. The Company recognizes rent expense on a straight-line basis over the term of the Cambridge Lease and records the difference between the amount charged to expense and the rent paid as a deferred rent liability. As of June 30, 2017, the amount of deferred rent liability was $208,000.

Pursuant to the terms of the non-cancelable lease agreements in effect at June 30, 2017, the future minimum rent commitments are as follows (in thousands):

Year Ended December 31,	
2017	647
2018	1,088
Total	$ 1,735

Total rent expense for the three-month periods ended June 30, 2017 and 2016 was $287,000 and $210,000, respectively. Total rent expense for the six-month periods ended June 30, 2017 and 2016 was $555,000 and $497,000, respectively.

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On March 31, 2016, the Company entered into a short-term lease with CRISPR Therapeutics, as subtenant, to sub-lease 5,233 square feet of the Facility (the "CRISPR Sublease"). The lease term was from April 1, 2016 through January 31, 2017. On March 31, 2016, the Company received $51,000 covering the first month's rent and a security deposit under the terms of the CRISPR Sublease. The funds received for the security deposit, $26,000, were classified as a component of accrued expenses on the balance sheet as of December 31, 2016. The CRISPR Sublease terminated on January 31, 2017 and the security deposit was returned to the subtenant.

On June 13, 2017, the Company entered into a short-term lease with Moderna Therapeutics, as subtenant, to sub-lease 5,233 square feet of the Facility (the "Moderna Sublease"). The lease term is from July 1, 2017 through October 26, 2018. On June 19, 2017, the Company received a $55,000 security deposit under the terms of the Moderna Sublease. This security deposit is classified as a component of accrued expenses on the balance sheet as of June 30, 2017.

Compensation Arrangement

The Company entered into a compensation arrangement with an executive during September 2016 which provided for a future cash payment by the Company to the executive based on the February 13, 2017 stock price of the executive's former employer. The award is earned over a period of one year. The expense related to the compensation arrangement was $87,000 and $174,000 for the three-month and six-month periods ended June 30, 2017, respectively. The final payment was determined on February 13, 2017 and the unearned portion is classified as a prepaid expense included within prepaid expenses and other current assets on the balance sheet. This prepaid expense is being amortized on a straight-line basis until the one year service period ends in September 2017.

Litigation

Lawsuits with Former Employee

In November 2013, the Company filed a lawsuit against Francis Reynolds, its former Chairman, Chief Executive Officer and Chief Financial Officer, in Middlesex Superior Court, Middlesex County, Massachusetts (InVivo Therapeutics Holdings Corp. v. Reynolds, Civil Action No. 13-5004). The complaint alleges breaches of fiduciary duties, breach of contract, conversion, misappropriation of corporate assets, unjust enrichment, and corporate waste, and seeks monetary damages and an accounting. The lawsuit involves approximately $500,000 worth of personal and/or exorbitant expenses that the Company alleges Mr. Reynolds inappropriately caused it to pay while he was serving as the Company's Chief Executive Officer, Chief Financial Officer, President, and Chairman of the Company's Board of Directors. On December 6, 2013, Mr. Reynolds answered the complaint, and filed counterclaims against the Company and the Company's Board of Directors. The counterclaims allege two counts of breach of contract, two

counts of breach of the covenant of good faith and fair-dealing, and tortious interference with a contract, and seek monetary damages and a declaratory judgment. The counterclaims related to Mr. Reynolds's allegations that the Company and the Company's Board of Directors interfered with the performance of his duties under the terms of his employment agreement, and that Mr. Reynolds was entitled to additional shares upon the exercise of certain stock options that he did not receive. On January 9, 2014, the Company, along with the directors named in the counterclaims, filed the Company's answer. Discovery has now been completed and the Company's motion for summary judgment on all counts of the complaint and Reynolds' opposition to the motion for summary judgment was filed with the court on March 3, 2017. On May 11, 2017, the Court heard oral argument on the Company's summary judgment motion and took the motion under advisement.

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

On July 22, 2016, Mr. Reynolds filed a lawsuit against the Company, certain present and former members of the Company's Board of Directors, and an employee of the Company in Hillsborough County Superior Court, Southern District, Hillsborough County, New Hampshire (Reynolds v. InVivo Therapeutics Holdings Corp, et al.) alleging defamation, conspiracy, and tortious interference, and seeking monetary damages. In August 2016, the lawsuit was removed to the United States District Court for the District of New Hampshire. The Company filed a motion to dismiss this action and after oral argument on November 28, 2016, the Court on November 30, 2016

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issued an order dismissing the case for lack of personal jurisdiction. The judgment was entered on the docket on December 1, 2016, and the deadline for appealing that decision has passed.

7. ACCRUED EXPENSES

Accrued expenses consisted of the following:

(In thousands)	June 30, 2017	December 31, 2016
Accrued bonus	$ 699	$ 906
Accrued payroll	107	126
Accrued vacation	214	91
Accrued severance	187	385
Other accrued expenses	686	451
Total accrued expenses	$ 1,893	$ 1,959

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 $2.0 million line of credit from the Commonwealth of Massachusetts’ Emerging Technology Fund, with $200,000 designated to be used for working capital purposes and the remainder to be used for the purchase of capital equipment. The annual interest rate on the loan is fixed at 6.5% with interest-only payments for the first thirty months, commencing on November 1, 2012, and then equal installments of interest and principal over the next fifty-four months, until the final maturity of the loan on October 5, 2019. Commencing on May 1, 2015, equal monthly payments of $41,000 are due until loan maturity. For the remainder of the year ending December 31, 2017, $215,000 will be due, and for the years ending December 31, 2018 and 2019, $452,000 and $400,000, respectively, will be due. In October 2012, as part of the agreement, the Company issued MassDev a warrant for the purchase of 9,037 shares of the Company’s common stock. The warrant has a seven-year term and is exercisable at $6.64 per share. The fair value of the warrant was determined to be $32,000 and is being amortized through interest expense over the life of the note. Amortization expense was $1,000 in each of the three-month periods ended June 30, 2017 and 2016, and $2,000 in each of the six-month periods ended June 30, 2017 and 2016. This amortization expense was included in interest expense in the Company’s consolidated statements of operations. The equipment line of credit is secured by substantially all the assets of the Company, excluding intellectual property. Interest expense related to this loan for the three-month periods ended June 30, 2017 and 2016 was $19,000 and $26,000, respectively. Interest expense related to this loan for the six-month periods ended June 30, 2017 and 2016 was $39,000 and $53,000, respectively.

9.COMMON STOCK

The Company has authorized 100,000,000 shares of common stock, $0.00001 par value per share, of which 32,175,179 shares were issued and outstanding as of June 30, 2017 and 32,044,087 shares were issued and outstanding as of December 31, 2016.

During the six-month period ended June 30, 2017, the Company issued an aggregate of 89,387 shares of common stock upon the exercise of stock options and received cash proceeds from such exercises of $26,000.

During the six-month period ended June 30, 2017, the Company issued an aggregate of 33,369 shares of common stock with a fair value of $113,000 to the Company’s 401(k) plan as a matching contribution.

During the six-month period ended June 30, 2017, the Company issued an aggregate of 7,986 shares of common stock under the Company’s Employee Stock Purchase Plan (the “ESPP”) and received cash proceeds of approximately $29,000.

During the year ended December 31, 2016, the Company issued an aggregate of 135,205 shares of common stock upon the exercise of stock options and received cash proceeds from such exercises of $191,000.

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During the year ended December 31, 2016, the Company issued an aggregate of 4,979 shares of common stock upon the cashless exercise of warrants.

During the year ended December 31, 2016, the Company issued an aggregate of 37,528 shares of common stock with a fair value of $208,000 to the Company's 401(k) plan as a matching contribution.

During the year ended December 31, 2016, the Company issued an aggregate of 16,729 shares of common stock under the ESPP and received cash proceeds of $91,000.

In March 2016, the Company closed an underwritten public offering of an aggregate of 4,293,333 shares of common stock and warrants to purchase an aggregate of 2,146,666 shares of common stock at a price to the public of $7.49 per share of common stock and $0.01 per warrant. The net proceeds to the Company, after deducting underwriting discounts and offering expenses, were approximately $29.9 million. The warrants have a per share exercise price of $10.00, or approximately 133% of the public offering price of the common stock, are exercisable immediately, and expire on March 18, 2021. The warrants contain a cashless exercise feature whereby shares are withheld to cover the exercise cost and the warrant holder receives a net issuance of the remaining shares. The Company is utilizing the net proceeds from the offering to fund ongoing clinical trials and for general corporate purposes.

10.STOCK OPTIONS

In 2007, the Company's Board of Directors adopted, and the Company's shareholders subsequently approved, the 2007 Employee, Director and Consultant Stock Plan (the "2007 Plan"). Pursuant to the 2007 Plan, the Company's Board of Directors (or committees and/or executive officers delegated by the Board of Directors) may grant incentive and nonqualified stock options to the Company's employees, officers, directors, consultants and advisors.

On October 26, 2010, the Company's Board of Directors adopted, and the Company's shareholders subsequently approved, the 2010 Equity Incentive Plan (as subsequently amended, the "2010 Plan"). The 2010 Plan provided for grants of incentive stock options to employees, and nonqualified stock options and restricted common stock to employees, consultants, and non-employee directors of the Company.

In April 2015, the Company's Board of Directors adopted, and the Company's shareholders subsequently approved, the 2015 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan provides for grants of incentive stock options to employees, and nonqualified stock options, restricted common stock, restricted stock units, and stock appreciation rights to employees, consultants, and non-employee directors of the Company.

As of June 30, 2017, the total number of shares authorized for issuance under the 2015 Plan was 4,322,355 shares, consisting of 4,000,000 initially approved under the 2015 Plan shares plus the 322,355 shares that remained available for grant under the 2010 Plan at the time of its termination. Upon approval of the 2015 Plan by the Company's shareholders on June 16, 2015, the 2010 Plan was terminated and no additional shares or share awards have been subsequently granted under the 2010 Plan.

Options issued under the 2007 Plan, 2010 Plan, and 2015 Plan (collectively, the "Plans") are exercisable for up to 10 years from the date of issuance.

As of June 30, 2017, there were outstanding options to purchase an aggregate of 2,233,050, 1,721,246 and 46,476 shares under the 2015 Plan, 2010 Plan, and 2007 Plan, respectively. As of December 31, 2016, there were outstanding options to purchase an aggregate of 1,222,085, 1,821,487 and 150,207 shares under the 2015 Plan, 2010 Plan, and 2007 Plan, respectively.

In March 2015, the Company's Board of Directors adopted, and the Company's shareholders subsequently approved, the ESPP. The ESPP allows employees to buy company stock twice per year through after-tax payroll deductions at a discount from market. The Company's Board of Directors initially authorized 187,500 shares for issuance under the ESPP. Commencing on the first day of the year ended December 31, 2016 and on the first day of each year thereafter during the term of the ESPP, the number of shares of common stock reserved for issuance shall be increased by the lesser of (i) 1% of the Company's outstanding shares of common stock on such date, (ii)

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50,000 shares, or (iii) a lesser amount determined by the Board of Directors. Under the terms of the ESPP, in no event shall the aggregate number of shares reserved for issuance during the term of the ESPP exceed 1,250,000 shares. As of June 30, 2017 and December 31, 2016, there were 262,785 and 220,771 shares reserved for issuance under the ESPP, respectively.

The ESPP is considered a compensatory plan with the related compensation cost recognized over each six-month offering period. As of June 30, 2017, $22,000 of employee payroll deductions have been withheld since January 1, 2017, the commencement of the current offering period, and are included in accrued expenses on the balance sheet. The compensation expense related to the ESPP for the three-month periods ended June 30, 2017 and 2016 was $8,000 and $1,000, respectively, and is included in share-based compensation expense. The share-based compensation expense related to the ESPP for the six-month periods ended June 30, 2017 and 2016 was $13,000 and $2,400.

Share-based compensation

For the three-month periods ended June 30, 2017 and 2016, the Company recorded stock-based compensation expense of $1.3 million and $1.2 million, respectively, inclusive of the expense related to the ESPP. For the six-month periods ended June 30, 2017 and 2016, the Company recorded stock-based compensation expense of $2.6 million and $2.4 million, respectively, inclusive of the expense related to the ESPP. Stock-based compensation expense for the three-month and six-month periods ended June 30, 2017 includes $24,000 of expense related to a stock option modification. As discussed above, the Company adopted ASU 2016-09 on January 1, 2017. Prior to the adoption of this standard, the Company recognized share-based compensation, net of estimated forfeitures, over the vesting period of the grant. Upon adoption of ASU 2016-09, the Company elected to change its accounting policy to recognize forfeitures as they occur. The Company continues to recognize share-based compensation expense over the vesting period of the grant. The new forfeiture policy election was adopted using a modified retrospective approach with a cumulative effect adjustment of $155,000 recorded to accumulated deficit on the balance sheet as of January 1, 2017.

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

A summary of option activity as of June 30, 2017 and changes for the six-month 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, 2016	3,193,785	$ 7.52		
Granted	1,114,463	$ 4.34		
Forfeited	(218,089)	$ 8.21		
Exercised	(89,387)	$ 0.29		
Outstanding at June 30, 2017	4,000,772	$ 6.76	7.65	$ 116,629
Vested at June 30, 2017	1,963,220	$ 7.94	6.29	$ 116,410

The weighted average grant-date fair value of options granted during the six-month period ended June 30, 2017 was $3.54 per share. The total fair value of options that vested in the three-month period ended June 30, 2017 was $1.0 million. The total fair value of options that vested in the six-month period ended June 30, 2017 was $2.0 million. As of June 30, 2017, total unrecognized compensation expense related to non-vested share-based option compensation arrangements amounted to $8.7 million and is estimated to be recognized over a period of 2.56 years.

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11. WARRANTS

The following table presents information about warrants to purchase common stock issued and outstanding at June 30, 2017:

Year Issued	Classification	Number of Warrants	Exercise Price	Date of Expiration
2010	Equity	343,931	$ 5.60	10/26/2017 - 12/3/2017
2010	Equity	306,838	$ 4.00	8/30/2017 - 12/3/2017
2012	Equity	6,054	$ 6.64	10/5/2019
2014	Liability	587,950	$ 3.87	5/9/2019
2016	Equity	2,146,666	$ 10.00	3/18/2021
Total		3,391,439		
Weighted average exercise price			$ 7.94	
Weighted average life in years				2.74

In March 2016, the Company closed an underwritten public offering of an aggregate of 4,293,333 shares of common stock and warrants to purchase an aggregate of 2,146,666 shares of common stock, at a price to the public of $7.49 per share of common stock and $0.01 per warrant. The net proceeds to the Company, after deducting underwriting discounts and offering expenses, were approximately $29.9 million.

The warrants have a per share exercise price of $10.00, or approximately 133% of the public offering price of the common stock issued in the March 2016 offering, and expire on March 18, 2021. 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, or similar transaction, among other events as described in the warrants. In the event that shares of common stock underlying the warrants are no longer registered under the Securities Exchange Act of 1934, as amended, the holder may, in its sole discretion, exercise the warrant in whole or in part and, in lieu of making cash payment, elect instead to receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant.

The fair value of the warrants was estimated at $11.7 million using a Black-Scholes model with the following assumptions: expected volatility of 112.8%, risk free interest rate of 1.3%, expected life of five years, and no dividends.

The Company assessed whether the warrants required accounting as derivatives. With the exception of the warrants issued in 2014 (Note 12), the Company determined that the warrants were (1) indexed to the Company's own stock and (2) classified in stockholders' equity in accordance with FASB Accounting Standards Codification Topic 815, Derivatives and Hedging. As such, the Company concluded that the warrants meet the scope exception for determining whether the instruments require accounting as derivatives and accordingly are classified in stockholders' equity.

12. DERIVATIVE INSTRUMENTS

The warrants issued in connection with the Company's May 2014 public offering to purchase 1,750,156 shares of common stock have anti-dilution protection provisions and, under certain conditions, require the Company to automatically reprice the warrants. Accordingly, these warrants are accounted for as derivative warrant liabilities. The Company used the Binomial Lattice option pricing model and assumptions that consider, among other factors, the fair value of the underlying stock, risk-free interest rate, volatility, expected life, and dividend rates in estimating fair value for the warrants considered to be derivative instruments. Changes in the fair value of the derivative warrant liabilities are recognized currently in the Company's consolidated statement of operations as a non-cash derivative gain or loss. For the three-month periods ended June 30, 2017 and 2016, the Company recorded a gain of $554,000 and $595,000, respectively, in other income (expense) in the statement of operations. For the six-month periods ended June 30, 2017 and 2016, the Company recorded a gain of $795,000 and a loss of $452,000, respectively, in other income (expense) in the statement of operations.

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The fair value of these derivative instruments at June 30, 2017 and December 31, 2016 was $519,000 and $1.3 million, respectively, and included as a derivative warrant liability in current liabilities on the balance sheet. The assumptions used principally in determining the fair value of the warrants were as follows:

	June 30, 2017		December 31, 2016	
Risk free interest rate	1.4	%	1.2	%
Expected dividend yield	—	%	—	%
Contractual term (in years)	1.9		2.4	
Expected volatility	82	%	89	%

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

The table below presents the changes in the derivative warrant liability during the three-month and six-month periods ended June 30, 2017 and 2016:

	Three Months Ended June 30,	
	2017	2016
Balance at March 31,	$ 1,073	$ 2,954
Fair value of warrants issued	—	—
Reduction in derivative liability due to exercise and modification of warrants	—	—
Increase (decrease) in the fair value of warrants	(554)	(595)
Balance at June 30,	$ 519	$ 2,359

	Six Months Ended June 30,	
	2017	2016
Balance at December 31,	$ 1,314	$ 1,907
Fair value of warrants issued	—	—
Reduction in derivative liability due to exercise and modification of warrants	—	—
Increase in the fair value of warrants	(795)	452
Balance at June 30,	$ 519	$ 2,359

The Company's March 2016 public offering resulted in a repricing of the existing warrants. The warrants' prices were decreased from $5.75 per share to $3.87 per share. In addition, the number of warrants increased from 395,716 to 587,950. The decrease in the liability for the six-month period ended June 30, 2017 was primarily driven by the decrease in the fair value of the underlying stock price since December 31, 2016.

13. NET LOSS PER COMMON SHARE

Basic and diluted net loss per share of common stock has been computed by dividing net loss by the weighted average number of shares outstanding during the period. Diluted net income per share of common stock is computed by dividing net income by the weighted average number of shares outstanding plus the dilutive effect, if any, of outstanding stock options, warrants and convertible securities. In a net loss period, options, warrants related to the Company's May 2014 capital raise, which include an antidilution provisions, and convertible securities are anti-dilutive and therefore excluded from diluted loss per share calculations.

For the three-month and six-month periods ended June 30, 2017 and 2016, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive:

	June 30,	
	2017	2016
Stock options	4,000,772	3,152,775
Warrants	3,391,439	3,484,445
	7,392,211	6,637,220

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14. SUBSEQUENT EVENTS

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

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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, 2016 (the "2016 Annual Report"). The management's discussion and analysis contains forward-looking statements within the meaning of the safe harbor provisions under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements include statements made regarding our commercialization strategy, future operations, cash requirements and liquidity, capital requirements, and other statements on our business plans and strategy, financial position, and market trends. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "should," "believe," "plan," "intend," "anticipate," "target," "estimate," "expect," and other similar expressions. These forward-looking statements are subj to risks and uncertainties that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements in this Quarterly Report, including factors such as our ability to raise substantial additional capital to finance our planned operations and to continue as a going concern; our ability to execute our strategy and business plan; our ability to obtain regulatory approvals for our products, including the Neuro-Spinal Scaffold; our ability to successfully commercialize our current and future product candidates, including the Neuro-Spinal Scaffold; the progress and timing of our development programs; market acceptance of our products; our ability to retain management and other key personnel; our ability to promote, manufacture, and sell our products, either directly or through collaborative and other arrangements with third parties; and other factors detailed under "Risk Factors" in Part II, Item 1A of this Quarterly Report. These forward-looking statements speak only as of the date hereof. We do not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Quarterly Report, except as required by law.

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

Overview

We are a research and clinical-stage biomaterials and biotechnology company with a focus on treatment of spinal cord injuries ("SCIs"). Our mission is to redefine the life of the SCI patient, and we are developing treatment options intended to provide meaningful improvement in patient outcomes following SCI. Our approach to treating acute SCIs is based on our investigational Neuro-Spinal Scaffold™ implant, a bioresorbable polymer scaffold that is designed for

implantation at the site of injury within a spinal cord and is intended to treat acute SCI. We believe the Neuro-Spinal Scaffold is the only SCI therapy in development focused solely on treating acute SCI directly at the epicenter of the injury. The Neuro-Spinal Scaffold incorporates intellectual property licensed under an exclusive, worldwide license from Boston Children's Hospital and the Massachusetts Institute of Technology. We are continually evaluating other technologies and therapeutics that may be complementary to our development of the Neuro-Spinal Scaffold or offer the potential to bring us closer to our goal of redefining the life of the SCI patient. We have also entered into exclusive license/assignment agreements with the University of California, San Diego and James Guest, M.D., Ph.D. covering delivery methods and devices for one of our preclinical programs.

Our Clinical and Pre-Clinical Programs

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

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Neuro-Spinal Scaffold™ Implant for acute SCI

Our leading product under development is the Neuro-Spinal Scaffold, an investigational bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord. The Neuro-Spinal Scaffold is intended to promote appositional, or side-by-side, healing by supporting the surrounding tissue after injury, minimizing expansion of areas of necrosis, and providing a biomaterial substrate for the body's own healing/repair processes following injury. We believe this form of appositional healing may spare white matter, increase neural sprouting, and diminish post-traumatic cyst formation.

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

- Poly lactic-co-glycolic acid, a polymer that is widely used in resorbable sutures and provides the biocompatible support for Neuro-Spinal Scaffold; and

- Poly-L-Lysine, a positively charged polymer commonly used to coat surfaces in order to promote cellular attachment.

Because of the complexity of SCIs, it is likely that multi modal therapies will be required to maximize positive outcomes in SCI patients. In the future, we may attempt to further enhance the performance of our Neuro-Spinal Scaffold by multiple combination strategies involving electrostimulation devices, additional biomaterials, drugs approved by the U.S. Food and Drug Administration ("FDA"), or growth factors. We expect the Neuro-Spinal Scaffold to be regulated by the FDA as a Class III medical device.

The INSPIRE Study

Our Neuro-Spinal Scaffold is currently being studied in a 20-subject pivotal probable benefit study, formally known as The INSPIRE Study: InVivo Study of Probable Benefit of the Neuro-Spinal Scaffold for Safety and Neurologic Recovery in Subjects with Complete Thoracic AIS A Spinal Cord Injury, under our Investigational Device Exemption application for the treatment of neurologically complete thoracic traumatic acute SCI. The purpose of the study is to evaluate whether the Neuro-Spinal Scaffold implant is safe and demonstrates probable benefit for the treatment of complete T2 T12/L1 SCI. The primary endpoint is currently defined as the proportion of patients achieving an improvement of at least one American Spinal Injury Association Impairment Scale ("AIS") grade at six months' post implantation. Additional endpoints include a reduction in pain and improvements in sensory and motor scores, bladder and bowel function, Spinal Cord Independence Measure, and quality of life. The INSPIRE Study includes an Objective Performance Criterion ("OPC"), which is a measure of study success used in clinical studies designed to demonstrate safety and probable benefit in support of an Humanitarian Device Exemption ("HDE") approval. The OPC

for The INSPIRE Study is currently defined as 25% or more of the patients in the study demonstrating an improvement of at least one AIS grade at the six month post-implantation visit.

The FDA has approved The INSPIRE Study to enroll up to 30 patients. This allows us to account for events such as screen failures or deaths and still have 20 evaluable patients at the primary endpoint analysis of The INSPIRE Study. We may choose to enroll additional patients after 20 patients have received the Neuro-Spinal Scaffold implant to ensure that there are 20 evaluable patients with six months of follow-up data for the primary endpoint analysis. As of July 31, 2017, we had implanted a total of 19 patients in The INSPIRE Study, 16 of whom remained in follow-up. There have been three patient deaths in The INSPIRE Study, including the most recent patient to enroll in The INSPIRE Study. Because this represented the third mortality in The INSPIRE Study, based in part on discussions with the Data Safety Monitoring Board, in July 2017, we elected to implement a temporary halt to enrollment as we engaged with the FDA to determine whether any changes to patient enrollment criteria related to patients who may have a higher mortality risk or other study modifications are deemed necessary. The FDA responded formally with its recommendations and we are working on assessing the FDA’s recommendations and formulating a response as quickly as possible. While we are continuing our discussions with the FDA, we anticipate that we will implement certain protocol amendments. We will be required to seek FDA approval of these protocol amendments before we will be permitted to resume enrollment in the study. Enrolling patients will also require the approval of the Institutional Review Boards (“IRB”s) at each clinical site. We cannot be certain when enrollment will recommence or how quickly the IRBs will act to allow us to reopen sites.

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Of the 19 patients implanted in The INSPIRE Study, 16 patients are in follow-up and 11 of whom had reached the six-month primary endpoint visit. Of these 11, six had improved from complete AIS A SCI to incomplete SCI (one patient to AIS C and five patients to AIS B) at the six-month primary endpoint visit and five had not converted at that visit. Two of the six patients who converted and were assessed to have AIS B SCI at the six-month primary endpoint were later assessed to have improved to AIS C SCI at 12 and 24-month visits, respectively. Five of the patients in follow-up have not yet reached the six-month primary endpoint visit although one of these patients converted to AIS C at one month. Two patients were assessed to have improved from complete AIS A SCI to incomplete AIS B SCI, but each was later assessed to have reverted to complete AIS A SCI prior to the patient's six-month examination, one of whom was then assessed at the six-month visit to have converted back to AIS B.

We are targeting completion of enrollment of the study as currently designed in the first half of 2018, with submission of an HDE application in the second half of 2018. In 2016, the FDA accepted our proposed HDE modular shell submission and review process for the Neuro-Spinal Scaffold. The HDE modular shell is comprised of three modules: a preclinical studies module, a manufacturing module, and a clinical data module. As part of its review process, the FDA reviews modules, which are individual sections of the HDE submission, on a rolling basis. Following the submission of each module, the FDA reviews and provides feedback, typically within 90 days, allowing the applicant to receive feedback and potentially resolve any deficiencies during the review process. Upon receipt of the final module, which constitutes the complete HDE submission, the FDA will make a filing decision which may trigger the review clock for an approval decision. We submitted the first module in March 2017.

The FDA recommended that we include a randomized, concurrent control arm or appropriate comparator control group in the study as part of a study design consideration and reiterated this request in connection with the recent enrollment halt. As an alternative to a concurrent control group, we initiated the Contemporary Thoracic SCI Registry Study (the "CONTEMPO Registry Study"), which we believe is an appropriate comparator group. The CONTEMPO Registry Study will utilize existing databases and registries to develop a historical comparator that, to the extent possible, matches patients to those patients enrolled in The INSPIRE Study. The CONTEMPO Registry Study is designed to provide comprehensive natural history benchmarks for The INSPIRE Study results that include SCI patients with similar baseline characteristics treated since 2006. The CONTEMPO Registry Study includes data from the Christopher & Dana Reeve Foundation North American Clinical Trials Network Registry, as well as the Model Systems Registry and the European Multicenter Study about Spinal Cord Injury. We anticipate that there will be between 100 to 200 patients in the CONTEMPO Registry Study. We have submitted a protocol for the CONTEMPO Registry Study to the FDA. In addition, we are currently in discussions with the FDA regarding its request to include an appropriate comparator control group in our pivotal probable benefit trial. We believe that the current study design is sufficient to demonstrate safety and probable benefit in support of an HDE application for marketing approval. However, we cannot be certain whether the FDA will approve our HDE without additional information or studies.

Results to date may not be indicative of results for the entire study. We must obtain FDA approval before we can sell any of our product candidates in the United States and approval of similar regulatory authorities in countries outside the United States before we can sell our product candidates in such countries. Although The INSPIRE Study is currently structured with the OPC as the primary component for demonstrating probable benefit, the OPC is not the only variable that the FDA would evaluate when reviewing a future HDE application. Approval is not guaranteed if the OPC is met, and even if the OPC is not met, the FDA may approve a medical device if probable benefit is supported by a comprehensive review of all clinical endpoints and preclinical results, as demonstrated by the sponsor's

body of evidence. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates if such approval is denied or delayed.

Pilot Study in Acute, Cervical SCI

In addition to the thoracic pivotal study described above, we have also received approval from Health Canada to initiate an early feasibility human pilot study, as the initial phase of a larger pivotal study, of our Neuro-Spinal Scaffold under an Investigational Testing Authorization application for the treatment of complete, traumatic cervical acute SCI.

Although we would like to conduct a similar cervical study in the United States, the FDA disapproved our proposed study in the United States, pending submission of additional data from The INSPIRE Study. We remain in discussions with the FDA regarding the proposed study and are hopeful that data generated in The INSPIRE Study will support the commencement of a cervical SCI clinical trial in the United States.

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Preclinical Programs

In addition to our clinical programs, we have a preclinical development program focused on the treatment of chronic SCI or sequelae of chronic SCI such as pain or spasticity. Future product candidates, which may incorporate gene therapy, stem cells or drug ingredients, may enable the treatment of a broader population such as patients with chronic pain, spasticity or paralysis and would require separate regulatory approval.

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

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

We were incorporated on April 2, 2003 under the name of Design Source, Inc. On October 26, 2010, we acquired the business of InVivo Therapeutics Corporation, which was founded in 2005, and continued the existing business operations of InVivo Therapeutics Corporation as our wholly owned subsidiary.

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 and, in connection therewith, adopt certain accounting policies that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period.

On an ongoing basis, we evaluate our estimates and judgments for all assets and liabilities, stock-based compensation expense, and the fair value determined for stock purchase warrants classified as derivative liabilities. We base our estimates and judgments on historical experience, current economic and industry conditions, and on various other factors that we believe to be reasonable under the circumstances. Such factors form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. There have been no changes in our critical accounting policies and estimates from the disclosure provided in our 2016 Annual Report.

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

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Results of Operations

Comparison of the Three Months Ended June 30, 2017 and 2016

Research and Development Expenses

Research and development expenses consisted primarily of expenses related to contract research organizations and clinical sites, professional services, and payroll. Research and development expenses for the three months ended June 30, 2017 were $3.2 million, an increase of $416,000 (or 14.9%) compared to the three months ended June 30, 2016. The increase in research and development expenses for the three months ended June 30, 2017 is partially attributable to an increase in clinical trial costs of $335,000 due to an increase in the number of patients in The INSPIRE Study and the opening of additional clinical trial sites. The increase is also due to increases in consulting costs of $328,000, stock-based compensation expense of $68,000, and recruiting costs of $53,000, offset in part by decreases in contract services and lab supplies of $233,000, compensation-related expenses of $102,000, and travel costs of $15,000.

General and Administrative Expenses

General and administrative expenses consisted primarily of payroll, rent, and professional services. General and administrative expenses for the three months ended June 30, 2017 were $3.7 million, an increase of $725,000 (or 24.2%) compared to the three months ended June 30, 2016. The increase in general and administrative expenses for the three months ended June 30, 2017 is attributable to increases in compensation-related expenses of $330,000, consulting expense of $168,000, legal costs of $131,000, and facilities costs of $116,000. These increases were offset in part by a decrease in share-based compensation expense of $44,000.

Other Income and Expense

Other income for the three months ended June 30, 2017 was $586,000, which was comprised of interest income of $52,000, interest expense of $20,000, and a derivative gain of $554,000. Other income for the three months ended June 30, 2016 was $602,000, which was comprised of interest income of $36,000, interest expense of $29,000, and a derivative gain of $595,000.

Comparison of the Six Months Ended June 30, 2017 and 2016

Research and Development Expenses

Research and development expenses consisted primarily of expenses related to contract research organizations and clinical sites, professional services, and payroll. Research and development expenses for the six months ended June 30, 2017 were $6.6 million, an increase of $1.2 million (or 22.9%) compared to the six months ended June 30, 2016. The increase in research and development expenses for the six months ended June 30, 2017 is partially attributable to an increase in clinical trial costs of $718,000 due to an increase in the number of patients in The INSPIRE Study and the opening of additional clinical trial sites. The increase is also due to increases in consulting costs of $719,000 and stock-based compensation expense of $167,000, offset in part by decreases in compensation-related expenses of $213,000 and contract services and lab expenses of $198,000.

General and Administrative Expenses

General and administrative expenses consisted primarily of payroll, rent, and professional services. General and administrative expenses for the six months ended June 30, 2017 were $7.0 million, an increase of $1.0 million (or 16.9%) compared to the six months ended June 30, 2016. The increase in general and administrative expenses for the six months ended June 30, 2017 is attributable to increases in compensation-related expenses of $634,000, consulting costs of $205,000, facilities costs of $155,000, public relations costs of $41,000, travel costs of $31,000, and share-based compensation expense of $21,000. These increases were offset in part by a decrease in recruiting costs of $106,000.

Other Income and Expense

Other income for the six months ended June 30, 2017 was $864,000, which was comprised of interest income of $109,000, interest expense of $40,000, and a derivative gain of $795,000. Other expense for the six months ended June

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30, 2016 was $453,000, which was comprised of interest income of $91,000, interest expense of $92,000, and a derivative loss of $452,000.

Liquidity and Capital Resources

Since inception, we have devoted substantially all of our efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets, and raising capital. At June 30, 2017, we had total assets of $23.6 million, total liabilities of $4.6 million, and total stockholders' equity of $19.0 million. For the six months ended June 30, 2017, we recorded a net loss of $12.7 million and our accumulated deficit as of June 30, 2017 was $169.9 million.

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 fund our operations and sustain our product development efforts, for acquisition of technologies and intellectual property rights, for preclinical and clinical testing of our anticipated products, for pursuing regulatory approvals, for the acquisition of capital equipment, laboratory and office facilities, for establishment of production capabilities, for selling, general, and administrative expenses, and for other working capital requirements. We also expect that we will need to raise additional capital through a combination of equity offerings, debt financings, other third party funding, marketing and distribution arrangements and/or other collaborations, strategic alliances, and licensing arrangements.

Since our inception, we have historically financed our operations primarily through the sale of equity-related securities. In March 2016, we closed an underwritten public offering of an aggregate of 4,293,333 shares of common stock and warrants to purchase an aggregate of 2,146,666 shares of common stock at a price to the public of $7.49 per share of common stock and $0.01 per warrant. Our net proceeds, after deducting underwriting discounts and offering expenses, were approximately $29.9 million. The warrants have a per share exercise price of $10.00, or approximately 133% of the public offering price of the common stock, and expire on March 18, 2021. We are utilizing the net proceeds from the offering to fund ongoing clinical trials and for general corporate purposes.

At June 30, 2017, we had cash, cash equivalents, and marketable securities of $21.8 million. We believe our current cash, cash equivalents, and marketable securities are adequate to fund our operations into the beginning of the second quarter of 2018.

Net cash used in operating activities for the six months ended June 30, 2017 was $11.0 million as compared to net cash used in operating activities of $8.2 million for the six months ended June 30, 2016. The $2.8 million increase in net cash used in operating activities for the six months ended June 30, 2017 as compared to the same period in the prior year was primarily due to a $924,000 increase in our net loss, changes in working capital of $706,000, and a $1.2

million decrease in non-cash items primarily driven by the change in fair value of our derivative warrant liability.

We also have significant commitments that will require the use of cash in operating activities in future periods, including our obligations under current operating leases. At June 30, 2017, our total committed lease obligations amounted to $1.7 million including total commitments due for the remainder of 2017 under our operating leases of $0.6 million.

Net cash provided by investing activities for the six months ended June 30, 2017 was $4.0 million attributable primarily to sales of marketable securities of $12.3 million, partially offset by purchases of marketable securities of $8.3 million. This compares to net cash used in investing activities of $378,000 for the six months ended June 30, 2016 attributable primarily to purchases of marketable securities of $6.2 million, partially offset by sales of marketable securities of $5.9 million

Net cash used in financing activities was $153,000 for the six months ended June 30, 2017 consisting of loan repayments of $208,000, partially offset by proceeds from the exercise of stock options and Employee Stock Purchase Plan issuances of $55,000. This compares to net cash provided by financing activities of $29.8 million for the six months ended June 30, 2016 consisting of proceeds from our March 2016 offering of $29.9 million, ESPP issuances of $43,000, and stock option exercises of $36,000, offset in part by loan repayments of $194,000.

We intend to pursue opportunities to obtain additional financing in the future through equity and/or debt financings. We have filed with the United States Securities and Exchange Commission (“SEC”), and the SEC declared effective, a shelf registration statement which permits us to issue up to $150 million worth of common stock, warrants, or units consisting

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of common stock and warrants. Under this effective shelf registration, we have the flexibility to issue registered securities, from time to time, in one or more separate offerings or other transactions with the size, price, and terms to be determined at the time of issuance. Registered securities issued using this shelf registration statement may be used to raise additional capital to fund our working capital and other corporate needs, for future acquisitions of assets, programs or businesses, and for other corporate purposes.

We may pursue various other dilutive and non-dilutive funding alternatives upon the results of our ongoing pivotal probable benefit study or to the extent we require additional capital to proceed with development of some or all of our product candidates on the expected timelines. The source, timing, and availability of any future financing will depend principally upon market conditions and the status of our clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back, or eliminate some or all of our research and product development programs, planned clinical trials, and capital expenditures, or to license our potential products or technologies to third parties.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources.

Contractual Obligations

There were no material changes to our contractual obligations and commitments described under Management’s Discussion and Analysis of Financial Condition and Results of Operations in the 2016 Annual Report.

Item 3.Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates which could affect our operating results, financial position, and cash flows. We manage our exposure to these market risks through our regular operating and financing activities. We do not use derivative financial instruments for speculative or trading purposes. For a discussion of our market risk exposure, refer to Item 7A, “Quantitative and Qualitative Disclosures About Market Risk,” in our 2016 Annual Report. As of June 30, 2017, there were no material changes in our exposure to market risk compared to December 31, 2016.

Item 4.Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2017. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms promulgated by the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of the Company’s disclosure controls and procedures as of June 30, 2017, the Company’s chief executive officer and chief financial officer concluded that, as of such date, the Company’s disclosure controls and procedures were effective at the reasonable assurance level.

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Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1.Legal Proceedings.

Lawsuits with Former Employee

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, and corporate waste, and seeks monetary damages and an accounting. The lawsuit involves approximately $500,000 worth of personal and/or exorbitant expenses that we allege Mr. Reynolds inappropriately caused us to pay while he was serving as our Chief Executive Officer, Chief Financial Officer, President, and Chairman of our Board of Directors. On December 6, 2013, Mr. Reynolds answered the complaint, and filed counterclaims against us and our Board of Directors. The counterclaims allege two counts of breach of contract, two counts of breach of the covenant of good faith and fair-dealing, and tortious interference with a contract, and seek monetary damages and a declaratory judgment. The counterclaims related to Mr. Reynolds’s allegations that we and the Board of Directors interfered with the performance of his duties under the terms of his employment agreement, and that Mr. Reynolds was entitled to additional shares upon the exercise of certain stock options that he did not receive. On January 9, 2014, we, along with the directors named in the counterclaims, filed our answer. Discovery has now been completed and our motion for summary judgment on all counts of the complaint and Reynolds’ opposition to the motion for summary judgment was filed with the court on March 3, 2017. On May 11, 2017, the Court heard oral argument on our summary judgment motion and took the motion under advisement.

We intend to continue to defend ourselves against these claims and, to date, we have not recorded any provision for losses that may arise.

On July 22, 2016, Mr. Reynolds filed a lawsuit against us, certain present and former members of our Board of Directors, and an employee of ours in Hillsborough County Superior Court, Southern District, Hillsborough County,

New Hampshire (Reynolds v. InVivo Therapeutics Holdings Corp, et al.) alleging defamation, conspiracy, and tortious interference, and seeking monetary damages. In August 2016, the lawsuit was removed to the United States District Court for the District of New Hampshire. We filed a motion to dismiss this action and after oral argument on November 28, 2016, the Court on November 30, 2016 issued an order dismissing the case for lack of personal jurisdiction. The judgment was entered on the docket on December 1, 2016, and the deadline for appealing that decision has passed.

Item 1A. Risk Factors.

Certain factors may have a material adverse effect on our business, financial condition, and results of operations. You should consider carefully the risks and uncertainties described below, in addition to other information contained in this Quarterly Report on Form 10-Q, including our consolidated financial statements and related notes. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. If any of the following risks actually occurs, our business, financial condition, results of operations, and future prospects could be materially and adversely affected.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and have incurred significant losses since our inception.

We have incurred net losses each year since our inception, including net losses of $12.7 million for the six months ended June 30, 2017. As of June 30, 2017, we had an accumulated deficit of $169.9 million. We have a limited operating history on which to base an evaluation of our business and investors should consider the risks and difficulties frequently

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encountered by early-stage companies in new and rapidly evolving markets, particularly companies engaged in the development of medical devices. To date, we have not commercialized any products or generated any revenues from the sale of products, and we do not expect to generate any product revenues in the foreseeable future. We do not know whether or when we will generate revenue or become profitable. Moreover, we may allocate significant amounts of capital towards products and technologies for which market demand is lower than anticipated and, as a result, may not achieve expectations or may elect to abandon such efforts.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities related to our Neuro-Spinal Scaffold implant. Overall, we expect our research and development expenses to be substantial and to increase for the foreseeable future as we continue the development and clinical investigation of our current and future products. Our lead product candidate, the Neuro-Spinal Scaffold implant, is currently being studied in a pivotal probable benefit study and, as a result, we expect that it could be several years, if ever, before we have a product candidate ready for commercialization. Even if we obtain regulatory approval to market our Neuro-Spinal Scaffold implant or other products, our future revenues will depend upon the size of any markets in which our products have received approval, our ability to achieve sufficient market acceptance, reimbursement from third-party payers, and other factors.

We anticipate that we will continue to incur substantial losses for the foreseeable future and may never achieve or maintain profitability.

We expect to continue to incur significant expenses and increasing net losses for at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- continue our pivotal probable benefit study of our Neuro-Spinal Scaffold implant;
- continue the research and development of our other product candidates;
- have our product candidates manufactured for clinical trials and for commercial sale;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, protect, and expand our intellectual property portfolio; and
- continue our research and development efforts for new product opportunities.

To become and remain profitable, we must succeed in developing and commercializing our product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, developing additional product candidates, obtaining regulatory approval for these product candidates, and manufacturing, marketing, and selling any products for which we may obtain regulatory approval. We are only in the initial stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could depress the value of our Company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings, or even continue our operations. A decline in the value of our Company could cause you to lose all or part of your investment.

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 June 30, 2017 were prepared under the assumption that we will continue as a going concern. At June 30, 2017, we had cash, cash equivalents, and marketable securities of $21.8 million. Given our development plans, we estimate cash resources will be sufficient to fund our operations into the beginning of the second

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quarter of 2018. This estimate is based on assumptions that may prove to be wrong; expenses could prove to be significantly higher, leading to a more rapid consumption of our existing resources.

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. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all. Based on these factors, management determined that there is substantial doubt regarding our ability to continue as a going concern. Our independent registered public accounting firm expressed substantial doubt as to our ability to continue as a going concern in its report dated March 10, 2017 included in the Company's Form 10-K as filed with the Securities and Exchange Commission ("SEC") on March 10, 2017.

We will need additional funding in the future. If we are unable to raise capital when needed, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts.

We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our pivotal probable benefit study of, and seek regulatory approval for, our Neuro-Spinal Scaffold implant. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to manufacturing, marketing, sales, and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce, or eliminate our research and development programs or any future commercialization efforts.

Our future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- the scope, progress, results, and costs of preclinical development, laboratory testing, and clinical studies for our Neuro-Spinal Scaffold implant and any other product candidates that we may develop or acquire;

- future clinical trial results of our Neuro-Spinal Scaffold implant;

- the timing of, and the costs involved in, obtaining regulatory approvals for the Neuro-Spinal Scaffold implant if our pivotal probable benefit study is successful, and the outcome of regulatory review of the Neuro-Spinal Scaffold implant;

- the cost and timing of future commercialization activities for our products, if any of our product candidates are approved for marketing, including product manufacturing, marketing, sales, and distribution costs;

- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;

- the cost of having our product candidates manufactured for clinical trials in preparation for regulatory approval and in preparation for commercialization;

- the cost and delays in product development as a result of any changes in regulatory oversight applicable to our product candidates;

- our ability to establish and maintain strategic collaborations, licensing, or other arrangements and the financial terms of such agreements;

- the cost and timing of establishing sales, marketing, and distribution capabilities;

- the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing our intellectual property portfolio;

- the efforts and activities of competitors and potential competitors;

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· the effect of competing technological and market developments; and

· the extent to which we acquire or invest in businesses, products, and technologies.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive, and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, and if we are not successful in raising additional capital, we may not be able to continue as a going concern.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our product candidates on unfavorable terms to us.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, and other third-party funding alternatives including license and collaboration agreements. To raise additional capital or pursue strategic transactions, we may in the future sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock, which will dilute the ownership interest of our current stockholders, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our current stockholders. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us or that may reduce the value of our common stock. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce, or terminate our product development or commercialization efforts for our Neuro-Spinal Scaffold implant or any other product candidates that we develop or acquire.

Our ability to use our net operating loss carryforwards and tax credit carryforwards may be limited.

We have generated significant net operating loss carryforwards (“NOLs”) and research and development tax credits (“R&D credits”) as a result of our incurrence of losses and our conduct of research activities since inception. We generally are able to carry NOLs and R&D credits forward to reduce our tax liability in future years. However, our ability to utilize the NOLs and R&D credits is subject to the rules of Sections 382 and 383 of the Internal Revenue Code of 1986 (“the Code”), as amended, respectively. Those sections generally restrict the use of NOLs and R&D credits after an “ownership change.” An ownership change occurs if, among other things, the stockholders (or specified

groups of stockholders) who own or have owned, directly or indirectly, 5% or more of a corporation's common stock or are otherwise treated as 5% stockholders under Section 382 of the Code and the United States Treasury Department regulations promulgated thereunder increase their aggregate percentage ownership of that corporation's stock by more than 50 percentage points over the lowest percentage of the stock owned by these stockholders over the applicable testing period. In the event of an ownership change, Section 382 imposes an annual limitation on the amount of taxable income a corporation may offset with NOL carryforwards and Section 383 imposes an annual limitation on the amount of tax a corporation may offset with business credit (including the R&D credit) carryforwards. Any unused annual limitation may be carried over to later years until the applicable expiration date for the respective NOL or R&D credit carryforwards. We have completed several financings since our inception, which may have resulted in a change in control as defined by Sections 382 and 383 of the Code, or could result in a change in control in the future, but we have not completed an analysis of whether a limitation as noted above exists. We have not performed a Section 382 study yet, but we will complete an appropriate analysis before our tax attributes are utilized.

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

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employees, and could substantially increase our operating costs, without any offsetting increase in revenue. We may also acquire the right to use certain intellectual property through licensing agreements, which could substantially increase our operating costs. Acquisitions and licensing agreements 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 or licensing agreement, it is likely we would issue equity securities as a significant 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 operations 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 operations of the acquired business, or due to amortization or impairment costs for acquired goodwill and other intangible assets.

Risks Related to the Development, Regulatory Approval, and Commercialization of Our Product Candidates

We depend heavily on the success of one product candidate, the Neuro-Spinal ScaffoldTM implant, which is currently being studied in a pivotal probable benefit study. Even if we obtain favorable clinical results, we may not be able to obtain regulatory approval for, or successfully commercialize, our Neuro-Spinal Scaffold implant.

We currently have only one product candidate, the Neuro-Spinal Scaffold implant, in clinical development, and our business depends almost entirely on the successful clinical development, regulatory approval, and commercialization of that product candidate, which may never occur. We currently have no products available for sale, generate no revenues from sales of any products, and we may never be able to develop marketable products. Our Neuro-Spinal Scaffold implant, which is currently being studied in an ongoing pivotal probable benefit study, will require substantial additional clinical development, testing, manufacturing process development, and regulatory approval before we are permitted to commence its commercialization. Before obtaining regulatory approval via the Humanitarian Device Exemption ("HDE") pathway for the commercial sale of any product candidate, we must demonstrate through extensive preclinical testing and clinical trials that the product candidate does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Alternatively, if we were to seek premarket approval ("PMA") for our product candidates, that would require demonstration that the product is safe and effective for use in each target indication. This process can take many years. Of the large number of medical devices in development in the United States, only a small percentage successfully complete the United States Food & Drug Administration ("FDA") regulatory approval process and are commercialized. Accordingly, even if we are able to obtain the requisite capital to continue to fund our development and clinical programs, we may be unable to successfully develop or commercialize our Neuro-Spinal Scaffold implant or any other product candidate.

Our other programs are in preclinical development. The clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by the FDA and other government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidates.

We have experienced delays and may experience additional delays in our ongoing pivotal probable benefit study for our Neuro-Spinal Scaffold implant, and we do not know whether modifications to The INSPIRE Study will be necessary, including whether future clinical trials will need to be conducted and/or whether The INSPIRE Study will need to be redesigned. Further, we do not know whether The INSPIRE Study and patient enrollment will be completed on schedule, if at all. Clinical studies for other future product candidates, including those above, may experience delays or may not begin.

Before we can obtain regulatory approval for the sale of our Neuro-Spinal Scaffold implant, we must complete the pivotal probable benefit study. Our Neuro-Spinal Scaffold implant is currently being studied in a 20-subject pivotal study under our approved IDE application for the treatment of complete thoracic traumatic acute spinal cord injury. Our pivotal probable benefit study may not be successfully completed or may take longer than anticipated because of any number of factors, including potential delays in the enrollment of subjects in the study, the availability of scaffolds to supply to our clinical sites, failure to demonstrate safety and probable benefit of our Neuro-Spinal Scaffold implant, lack of adequate

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funding to continue the clinical trial, or unforeseen safety issues. For example, in July 2017, we implemented an enrollment halt for The INSPIRE Study following the death of a patient who had been implanted with the Neuro-Spinal Scaffold implant in June 2017. Although we believe that the death was not related to the Neuro-Spinal Scaffold implant or the implantation procedure, in July 2017, we halted enrollment while we engage with the FDA to determine whether any changes to patient enrollment criteria related to patients who may have a higher mortality risk or other study modifications are deemed necessary. The FDA responded formally with its recommendations and we are working on assessing the FDA's recommendations and formulating a response as quickly as possible. While we are continuing our discussions with the FDA, we anticipate that we will implement certain protocol amendments. We will be required to seek FDA approval of these protocol amendments before we will be permitted to resume enrollment in the study. Enrolling patients will also require the approval of the Institutional Review Boards ("IRB"s) at each clinical site. We cannot be certain when enrollment will recommence or how quickly the IRBs will act to allow us to reopen sites.

In addition, even though the initial results of our clinical studies in humans are promising, our results may subsequently fail to meet the safety and probable benefit standards required to obtain regulatory approvals. For example, in The INSPIRE Study, two patients were assessed to have improved from complete AIS A SCI to incomplete AIS B SCI, but each was later assessed to have reverted to complete AIS A SCI prior to the patient's six-month examination. At the six-month examinations, one patient had converted back to AIS B and the other remained at AIS A. There is known and published variability in some of the measures used to assess AIS improvement and these measures can vary over time or depending upon the examiner. While we have implemented procedures in our clinical trial to limit such variations, we cannot be certain that regulatory authorities will accept the results of our clinical trials or interpret them the way that we do. Although these reversions are not believed to be related to the scaffold, we submitted information regarding these cases to the FDA for its review. If the FDA has concerns regarding these cases, the recent death noted above, or other cases, they could decide to formally pause enrollment. In addition, we are currently in active discussions with the FDA regarding the set of clinical data that would support a future approval of the product. Modifications to our ongoing study due to those discussions may further delay completion of the study.

In addition, clinical trials can be delayed or aborted for a variety of reasons, including delay or failure to:

- obtain regulatory approval to commence future clinical trials;
- reach agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtain IRB approval at each site;
- recruit, enroll, and retain patients through the completion of clinical trials;

- maintain clinical sites in compliance with trial protocols through the completion of clinical trials;

- address patient safety concerns that arise during the course of the trial;

- initiate or add a sufficient number of clinical trial sites; or

- manufacture sufficient quantities of our product candidate for use in clinical trials.

We could encounter delays if a clinical trial is suspended or terminated by us, by the relevant IRB at the sites at which such trials are being conducted, by the Data Safety Monitoring Board ("DSMB") for such trial, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, a problematic inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse events, or changes in laws or regulations. For example, we halted enrollment in the study in association with a study death in July 2017 and must seek FDA and IRB approvals for changes to the study protocol before resuming enrollment. While we and the site investigators believe that the death is not related to our product or the implant procedure, this was the third death in The INSPIRE Study and represents a rate that is higher than in historical studies. Thus, we implemented an enrollment halt as we engaged with the FDA. The FDA has determined that we must seek the Agency's approval before resuming enrollment. Additionally, although the

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investigators and our independent DSMB believed that the first two deaths in The INSPIRE Study were not related to the Neuro-Spinal Scaffold implant or the implant procedure, the FDA has indicated that it remains unclear whether the causes of each of the deaths are related to implant procedure, patient eligibility criteria or study conduct. In addition, regulatory agencies may require an audit with respect to the conduct of a clinical trial, which could cause delays or increase costs. Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and regulatory review process, and jeopardize our ability to obtain approval and commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, and prospects significantly.

We may find it difficult to enroll patients in our clinical studies, which could delay or prevent clinical studies of our product candidates.

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical studies depends on the speed at which we can enroll patients to participate in testing our product candidates. If we have difficulty enrolling a sufficient number of patients to conduct our clinical studies as planned, we may need to delay, limit, or terminate ongoing or planned clinical studies, any of which would have an adverse effect on our business.

Patient enrollment is affected by a number of factors including:

- severity of the disease, injury, or condition under investigation;
- design of the study protocol;
- size and nature of the patient population;
- eligibility criteria for and design of the study in question;
- perceived risks and benefits of the product candidate under study;
- proximity and availability of clinical study sites for prospective patients;
- availability of competing therapies and clinical studies;

· efforts to facilitate timely enrollment in clinical studies;

· patient referral practices of physicians; and

· ability to monitor patients adequately during and after treatment.

For a period in 2016, as a result of an FDA pre-specified enrollment hold, we were unable to enroll patients in The INSPIRE Study pending FDA authorization to proceed with additional enrollment, which delayed our ability to open new sites and enroll patients at the pace we had anticipated. In addition, as of July 2017 we have halted enrollment in the study in relation to a recent death in the study. We must seek approval from the FDA before resuming enrollment. We may not be able to initiate or continue clinical studies if we cannot enroll a sufficient number of eligible patients to participate in the clinical studies required by regulatory agencies. If we have difficulty enrolling a sufficient number of patients to conduct our clinical studies as planned, we may need to delay, limit, or terminate ongoing or planned clinical studies, any of which would have an adverse effect on our business. In addition, subject to resolving the current enrollment hold, we may elect to enroll in excess of the 20 patients required for The INSPIRE Study in order to account for events such as screen failures, deaths, or other such events and still have 20 evaluable patients with six months of follow-up data for the primary endpoint analysis. This could delay submission of our HDE application, or delay review of it by the FDA.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier nonclinical studies and clinical trials may not be predictive of future trial results.

The results of preclinical studies and early clinical trials of new medical devices do not necessarily predict the results of later-stage clinical trials. The design of our clinical trials is based on many assumptions about the expected effects of our

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product candidates, and if those assumptions are incorrect, the trials may not produce results to support regulatory approval. We are currently pursuing marketing approval via our HDE which requires us to show the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit of health outweighs the risk of injury or illness from its use. Preliminary results may not be confirmed upon full analysis of the detailed results of an early clinical trial. Product candidates in later stages of clinical development may fail to show safety and probable benefit sufficient to support intended use claims despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidates may not be sufficient to obtain regulatory approval in the United States or elsewhere. It is also possible that patients enrolled in clinical trials will experience adverse events or unpleasant side effects that are not currently part of the product candidate's profile. Because of the uncertainties associated with clinical development and regulatory approval, we cannot determine if or when we will have an approved product for commercialization or achieve sales or profits.

We must obtain 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. 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 may not be approved, which could limit our potential revenues. Foreign regulatory authorities may apply similar or additional 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 product candidates are not approved, our ability to generate revenues will be limited and our business will be adversely affected.

We are currently pursuing an HDE regulatory pathway in the United States for our Neuro-Spinal Scaffold. The HDE requires that there is no other comparable device available to provide therapy for a condition and requires sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use. The amended protocol for The INSPIRE Study, which was approved in February 2016, established an Objective Performance Criterion ("OPC"), which is a measure of study success used in clinical studies designed to demonstrate safety and probable benefit in support of an HDE approval. The OPC for The INSPIRE Study is currently defined as 25% or more of the patients in the study demonstrating an improvement of at least one AIS grade by six months post-implantation. Although The INSPIRE Study is currently structured with the OPC as the primary criterion for demonstrating probable benefit, the OPC is not the only variable that the FDA would evaluate when reviewing an HDE application. Approval is not guaranteed if the OPC is met, but even if the OPC is not met, the FDA may approve a medical device if probable benefit is supported by a comprehensive review of all clinical endpoints and preclinical results, as demonstrated by the sponsor's body of evidence.

We are currently in discussions with the FDA regarding its request and suggestions for changes to our pivotal probable benefit trial. We believe that the current study design is sufficient to demonstrate safety and probable benefit in support of an HDE application for marketing approval. However, we cannot be certain whether the FDA will approve our HDE without additional information or studies. For example, the FDA has recommended that we include a randomized, concurrent control arm in the study as part of a study design consideration and reiterated this request in connection with the recent enrollment halt. As an alternative to a concurrent control, we initiated the Contemporary Thoracic SCI Registry Study (the "CONTEMPO Registry Study"), utilizing existing databases and registries, to develop a historical comparator that, to the extent possible, matches patients to those patients enrolled in The INSPIRE Study. There can be no assurance that the CONTEMPO Registry Study will be successfully completed. Even if we successfully complete the CONTEMPO Registry Study, we cannot be certain that the FDA will agree that this additional study provides sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use. Moreover, analysis of data from the CONTEMPO Registry Study may suggest amendments to the protocol for The INSPIRE Study, including adjustment to the existing OPC, which might create a higher threshold for evidencing probable benefit. For example, preliminary data from certain registries we are using in the CONTEMPO Registry Study indicate that the conversion rate

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may be higher than the approximately 15.5% rate from the historical registries that were the basis for the selection of the current OPC. While this preliminary data is still substantially lower than the conversion rates in The INSPIRE Study to date, we cannot be certain that we will not have to amend the protocol as a result of our discussions with the FDA, including to increase the OPC. In the event our assessment that the current study design, or any amended study design we propose, is not acceptable to the FDA, our ability to obtain approval under the HDE pathway may be delayed or may not be feasible. If the FDA does not approve our product candidates in a timely fashion, or at all, our business and financial condition will be adversely affected.

The 21st Century Cures Act recently increased the upper population limit for an HDE from 4,000 to 8,000, which allows us to potentially request an expansion of our current Humanitarian Use Device ("HUD") to include additional patient populations beyond our current HUD for complete spinal cord injury ("SCI"). If we choose to pursue such an expansion, this may cause our application to be delayed or cause the FDA to request additional information. In addition, our current study is not designed to support approval beyond complete SCI. Thus, expansion would require additional studies. We cannot be certain that we will be able to increase the potential population that we might be able to treat based on the HDE pathway. If any of these events occur, our business and financial condition will be adversely affected.

There are risks associated with pursuing FDA approval via an HDE pathway, including the possibility that the approval could be withdrawn in the future if the FDA subsequently approves another device for the same intended use, as well as limitations on the ability to profit from sales of the product.

If the FDA subsequently approves a PMA or clears a 510(k) for the HUD or another comparable device with the same indication, the FDA may withdraw the HDE. Once a comparable device becomes legally marketed through PMA approval or 510(k) clearance to treat or diagnose the disease or condition in question, there may no longer be a need for the HUD and so the HUD may no longer meet the requirements of section 520(m)(2)(B) of the Food Drug and Cosmetic Act ("FDCA").

Except in certain circumstances, products approved under an HDE cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (i.e., for profit). Currently, under section 520(m)(6)(A)(i) of the FDCA, as amended by the Food and Drug Administration Safety and Innovation Act, an HUD is only eligible to be sold for profit after receiving HDE approval if the device (1) is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or (2) is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe. If an HDE-approved device does not meet either of the eligibility criteria, the device cannot be sold for profit. The legislation related to HUD/HDE profit eligibility expires on October 1, 2017 and may or may not be renewed.

Some of our future products may be viewed by the FDA as combination products and the review of combination products is often more complex and more time consuming than the review of other types of products.

Our future products may be regulated by the FDA as combination products. As explained above in the Government Regulation section, for a combination product, the FDA must determine which center or centers within the FDA will review the product candidate and under what legal authority the product candidate will be reviewed. The process of obtaining FDA marketing clearance or approval is lengthy, expensive, and uncertain, and we cannot be sure that any of our combination products, or any other products, will be cleared or approved in a timely fashion, or at all. In addition, the review of combination products is often more complex and more time consuming than the review of a product candidate under the jurisdiction of only one center within the FDA. We cannot be sure that the FDA will not select to have our combination products reviewed and regulated by only one FDA center and/or different legal authority, in which case the path to regulatory approval would be different and could be more lengthy and costly. If the FDA does not approve or clear our products in a timely fashion, or at all, our business and financial condition will be adversely affected.

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

In general, the biotechnology industry is subject to intense competition and rapid and significant technological change. We have many potential competitors, including major drug companies, specialized biotechnology firms, academic

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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, design and implementation of clinical trials, regulatory processes and approval for products, production and manufacturing, and sales and marketing of approved products. Large and established companies compete in the biotechnology 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 if they have collaborative arrangements with larger and more established biotechnology 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, clinical 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.

The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.

Our ongoing research and development, preclinical testing, and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. We are currently conducting a pivotal study of our Neuro-Spinal Scaffold implant to gather information about the product’s safety and probable benefit. In the future, we may conduct clinical trials to support approval of new products. Clinical studies must be conducted in compliance with FDA regulations or the FDA may take enforcement action. The data collected from these clinical studies may ultimately be used to support market clearance for these products. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA will agree with our conclusions regarding them. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and preclinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate’s profile.

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 product candidates, the commercial success of our 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. Physicians and hospitals will need to establish training and procedures to utilize and implement our Neuro-Spinal Scaffold implant, and there can be no assurance that these parties will adopt the use of our device or develop sufficient training and procedures to properly utilize it. 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. Payers may view new products or products that have only recently been launched or with limited clinical data available, as investigational, unproven, or experimental, and on that basis may deny coverage of procedures involving use of our products. If our product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business.

If we or our suppliers fail to comply with FDA regulatory requirements, or if we experience unanticipated problems with any approved products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain regulatory approval, and the manufacturing processes, reporting requirements, post-approval clinical data, and promotional activities for such product, will be subject to continued regulatory review and oversight by the FDA. In particular, we and our third-party suppliers will be required to comply with the FDA’s Quality

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System Regulations ("QSRs"). These FDA regulations cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage, and shipping of products. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. If we, or our manufacturers, fail to adhere to QSR requirements, this could delay production of our product candidates and lead to fines, difficulties in obtaining regulatory clearances, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition and results of operations.

In addition, we and our suppliers are required to comply with Good Manufacturing Practices ("GMPs") and Good Tissue Practices ("GTPs") with respect to any human cells and biologic products we may develop, and International Standards Organization ("ISO") regulations for the manufacture of our products, and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, and shipping of any product for which we obtain clearance or approval. Manufacturing may also be subject to controls by the FDA for parts of the combination products that the FDA may find are controlled by the biologics regulations.

The FDA audits compliance with the QSR and other similar regulatory requirements through periodic announced and unannounced inspections of manufacturing and other facilities. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees, and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention, or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for premarket approval of new products or modified products;
- withdrawing PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Any of these sanctions could have a material adverse effect on our reputation, business, results of operations, and financial condition.

Our products and operations are subject to extensive governmental regulation both in the United States and abroad, and our failure to comply with applicable requirements could cause our business to suffer.

Our medical device and biologic products and operations are subject to extensive regulation by the FDA and various other federal, state, and foreign governmental authorities. For example, we expect to initiate a clinical trial in Canada and will be subject to applicable Canadian regulations as we initiate and conduct that trial. Government regulation of medical devices and biologic products is meant to assure their safety and effectiveness, and includes regulation of, among other things:

· design, development, and manufacturing;

· testing, labeling, content, and language of instructions for use and storage;

· clinical trials;

· product safety;

· marketing, sales, and distribution;

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- regulatory clearances and approvals including premarket clearance and approval;

- conformity assessment procedures;

- product traceability and record keeping procedures;

- advertising and promotion;

- product complaints, complaint reporting, recalls, and field safety corrective actions;

- post-market surveillance, including reporting of deaths or serious injuries, and malfunctions that, if they were to recur, could lead to death or serious injury;

- post-market studies; and

- product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations higher than anticipated costs or lower than anticipated sales.

Before we can market or sell a new regulated medical device product in the United States, we must obtain clearance under Section 510(k) of the FDCA, approval of a PMA, or approval of an HDE, unless the device is specifically exempt from premarket review. Our Neuro-Spinal Scaffold implant is expected to be regulated by the FDA as a Class III medical device, requiring either PMA or HDE approval. An HUD designation was granted for the Neuro-Spinal Scaffold implant in 2013, opening the HDE pathway.

In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing, and labeling data. Modifications to products that are approved through a PMA generally need FDA approval. The process of obtaining a PMA is costly and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA until an approval is obtained.

An HDE application is similar in form and content to a PMA and, although exempt from the effectiveness requirements of a PMA, an HDE does require sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use. Like a PMA, changes to HDE devices generally need FDA approval.

Biological products must satisfy the requirements of the Public Health Services Act and its implementing regulations. In order for a biologic product to be legally marketed in the U.S., the product must have a BLA approved by the FDA. The testing and approval process requires substantial time, effort, and financial resources, and each may take several years to complete.

The FDA can delay, limit, or deny clearance or approval of a product for many reasons, including:

· we may not be able to demonstrate to the FDA's satisfaction that our products are safe and effective for their intended uses;

· the data from our preclinical studies and clinical trials may be insufficient to support clearance or approval, where required; and

· the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions that may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis.

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In addition, even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct post-marketing studies. Failure to conduct required studies in a timely manner could result in the revocation of approval for the product that is subject to such a requirement and could also result in the recall or withdrawal of the product, which would prevent us from generating sales from that product in the United States.

Failure to comply with applicable laws and regulations could jeopardize our ability to sell our products and result in enforcement actions such as:

- warning letters;
- fines;
- injunctions;
- civil penalties;
- termination of distribution;
- recalls or seizures of products;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- refusal of the FDA or other regulators to grant future clearances or approvals;
- withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and/or
- in the most serious cases, criminal penalties.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, results of operations, and financial condition.

If our medical device products, or malfunction of our medical device products, cause or contribute to a death or a serious injury before or after approval, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers with approved products are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. Any such serious adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. In the context of our ongoing clinical trial, we report adverse events to the FDA in accordance with IDE regulations and to other relevant regulatory authorities in accordance with applicable national and local regulations. Any corrective action, whether voluntary or involuntary, and either pre- or post-market, needed to address any serious adverse events will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Our medical device products, once approved, may in the future be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

If our products are approved for commercialization, the FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is

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reasonable probability that the device would cause serious injury or death. A government-mandated or voluntary recall by us or one of our partners could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects, or other deficiencies and issues. Recalls of any of our commercialized products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations, and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits.

If we obtain approval for our products, we may be subject to enforcement action if we engage in improper marketing or promotion of our products.

We are not permitted to promote or market our investigational products. After approval, our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or off-label, use. Surgeons may use our products off-label, as the FDA does not restrict or regulate a surgeon's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine, or criminal penalties. It is also possible that other federal, state, or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products could be impaired. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us, and harm our reputation.

If we obtain approval for our products, their commercial success will depend in part upon the level of reimbursement we receive from third parties 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 our 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.

Legislative or regulatory reform of the healthcare systems in which we operate may affect our ability to commercialize our product candidates and could adversely affect our business.

The government and regulatory authorities in the United States, the European Union, and other markets in which we plan to commercialize our product candidates may propose and adopt new legislation and regulatory requirements relating to the approval, CE marking, manufacturing, promotion, or reimbursement of medical device and biologic products. It is impossible to predict whether legislative changes will be enacted or applicable regulations, guidance, or interpretations changed, and what the impact of such changes, if any, may be. Such legislation or regulatory requirements, or the failure to comply with such, could adversely impact our operations and could have a material adverse effect on our business, financial condition, and results of operations.

For example, on September 26, 2012, the European Commission adopted a package of legislative proposals designed to replace the existing regulatory framework for medical devices in the European Union. These proposals are intended to strengthen the medical devices rules in the European Union. On June 17, 2016, the Dutch Presidency of the Council of the European Union formally informed the Council of Ministers of the agreement that was reached on May 25, 2016 with the European Parliament as part of the discussion concerning the text of the proposed Medical Devices Regulation (“MDR”) and the In Vitro Diagnostic Medical Devices Regulation (“IVDR”). On February 22, 2017, after finalization of a final linguistic review of the texts and the last revisions, the final text of the MDR and IVDR were published on the Council of the European Union's website. The regulations were adopted by the Council and the European Parliament in April 2017. The regulations, which will substantially impact medical devices manufacturers, will be applicable from May 2020 for the MDR and May 2022 for the IVDR. When applicable, the MDR may prevent or delay the CE marking of our products under development or impact our ability to modify our currently CE marked products on a timely basis.

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Similarly, in the United States, legislative changes have been enacted in the past and further changes are proposed that would impact the Affordable Care Act. These new laws may result in additional reductions in Medicare and other healthcare funding. Beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, on average, to 2025. It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing healthcare legislation. The Affordable Care Act has faced ongoing legal challenges, including litigation seeking to invalidate some of or all of the law or the manner in which it has been implemented. With the new Presidential administration and Congress, there may be additional legislative changes, including repeal and replacement of certain provisions of the Affordable Care Act. It remains to be seen, however, whether new legislation will be enacted and, if so, precisely what any new legislation will provide and what impact it will have on the availability of healthcare and containing or reducing healthcare costs. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. Because of the continued uncertainty about the effects, implementation, and potential repeal or modification of the Affordable Care Act and other federal healthcare legislation, we cannot quantify or predict with any certainty the likely impact of the Affordable Care Act, its amendment or repeal, or any alternative or related legislation, or any implementation of any such legislation, on our business model, prospects, financial condition, and results of operations.

In addition, in June 2016, eligible members of the electorate in the United Kingdom decided by referendum to exit the European Union, which is commonly referred to as Brexit. On March 29, 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the referendum could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union. We are currently planning to open sites for The INSPIRE Study and anticipate that we will be subject to applicable U.K. regulations. Because of the continued uncertainty about the effects, implementation, or potential repeal of Brexit, we cannot quantify or predict with any certainty the likely impact of Brexit or related legislation on our business model, prospects, financial condition, and results of operations.

These and other legislative and regulatory changes that have been or may be proposed in the future may impact our ability to successfully commercialize our product candidates.

We have limited experience manufacturing our Neuro-Spinal ScaffoldTM implant for clinical-study scale and no experience for commercial scale.

To date, we have manufactured our Neuro-Spinal Scaffold implant on a small scale, including sufficient supply that is needed for our clinical studies. We may encounter unanticipated problems in the scale-up process that will result in delays in the manufacturing of the Neuro-Spinal Scaffold implant and therefore delay our clinical studies. During our clinical trials, we are subject to FDA regulations requiring manufacturing of our scaffolds with the FDA requirements for design controls and 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.

Risks Related to Our Intellectual Property

We license certain technology underlying the development of our Neuro-Spinal Scaffold from BCH and MIT, and the loss of the license would result in a material adverse effect on our business, financial position, and operating results and cause the market value of our common stock to decline.

We license technology from Boston Children's Hospital ("BCH") and the Massachusetts Institute of Technology ("MIT") that is integrated into our Neuro-Spinal Scaffold implant under an exclusive license. Under the license agreement, we have agreed to milestone payments and to meet certain reporting obligations. In the event that we were to breach any of the obligations under the agreement and fail to timely cure, BCH and MIT would have the right to terminate the

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agreement upon notice. In addition, BCH and MIT have the right to terminate our license upon the bankruptcy or receivership of the Company. If we are unable to continue to use or license this technology on reasonable terms, or if this technology fails to operate properly, we may not be able to secure alternatives in a timely manner and our ability to develop our products could be harmed.

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 our 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.

Risks Related to our Dependence on Third Parties

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 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 of our product candidates for reasons both within and outside of our control.

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

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We rely on third-party suppliers and vendors for certain 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.

If the third parties on which we rely to conduct our laboratory testing, animal, and human clinical trials do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our products.

We have been, and will continue to be, dependent on third-party CROs, medical institutions, investigators, and contract laboratories to conduct certain of our laboratory testing, animal and human clinical 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 these 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 preclinical development activities or clinical trials may be extended, delayed, suspended, or terminated, and we may not be able to obtain regulatory approval or successfully commercialize our products on a timely basis, if at all, and our business, operating results, and prospects may be adversely affected.

Risks Related to Employee Matters and Managing Growth

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 personnel. The loss of any of these individuals 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 senior management or other 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.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from collaborators, prospective licensees, and other third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

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Risks Related to Litigation and Legal Compliance

We are, and in the past have been, subject to lawsuits, which could divert management's attention and harm our business.

We are involved in litigation with our former Chairman, Chief Executive Officer, and Chief Financial Officer. We were previously the subject of a securities derivative lawsuit and a securities class action lawsuit, both of which were dismissed in January 2017. We may face additional lawsuits, including class action or securities derivative lawsuits. The amount of time that is required to resolve these lawsuits is unpredictable and any lawsuits may divert management's attention from the day-to-day operations of our business, which could adversely affect our business, results of operations, and cash flows. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. See "Legal Proceedings" above for further information regarding our litigation.

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

We will have exposure to claims for product liability. Product liability coverage for the healthcare industry is expensive and sometimes difficult to obtain. We may not be able to maintain such insurance on acceptable terms or be able to secure increased coverage if the commercialization of our products progresses, nor can we be sure that existing or future claims against us will be covered by our product liability insurance. Moreover, the existing coverage of our insurance policy or any rights of indemnification and contribution that we may have may not be sufficient to offset existing or future claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable terms, 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 our management's attention.

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 environmental, health, and safety laws and regulations, including those 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. 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 and development efforts.

Our relationships with customers and third party payers will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm, and diminished profits and future earnings.

Healthcare providers, physicians, and third party payers will play a primary role in the recommendation and use of our products and any other product candidates for which we obtain marketing approval. Our future arrangements with healthcare providers, physicians, and third party payers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

· the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order, or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

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- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered products to report payments and other transfers of value to physicians and teaching hospitals; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws and transparency statutes, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payers, including private insurers.

Some state laws require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require product manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment, or restructuring of our operations could adversely affect our financial results. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and

administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs.

Risks Related to Investment in Our Securities

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

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

· the status, completion, and/or results of our clinical trials;

· actual or anticipated variations in our operating results;

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- announcements of developments by us or our competitors;
- 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;
- 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.

As of June 30, 2017, there were outstanding warrants to purchase 3,391,439 shares of our common stock, and outstanding options to purchase 4,000,772 shares of our common stock. We expect to issue additional equity awards to compensate employees, consultants, and directors, and may issue additional shares 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 current stockholders. The future issuance of any such additional shares of common stock 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 convertible securities in the future in conjunction with any capital raising efforts, including at a price (or exercise prices) below the price at which shares of our common stock are currently quoted on the Nasdaq Global Market.

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 our 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 believe that 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.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The Exhibits listed in the Exhibit Index immediately preceding such Exhibits are filed with or incorporated by reference in this Quarterly Report on Form 10-Q.

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SIGNATURES

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

INVIVO THERAPEUTICS HOLDINGS CORP.

Date: August 8, 2017 By: /s/ Christopher McNulty
Name: Christopher McNulty
Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

Exhibit Number	Description
10.1	Consulting Agreement, dated as of June 29, 2017, between the Company and Richard Toselli, M.D.
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