INVIVO THERAPEUTICS HOLDINGS CORP.
Form 424B3
November 08, 2018

Filed pursuant to Rule 424(b)(3)
Registration Statement Nos. 333 224424 and 333 225768

PROSPECTUS SUPPLEMENT NO. 3

(TO PROSPECTUS DATED JUNE 20, 2018)

INVIVO THERAPEUTICS HOLDINGS CORP.

388,403 shares of Common Stock and

388,403 Warrants to purchase shares of Common Stock

and

6,242,811 Pre-Funded Warrants to purchase shares of Common Stock and

6,242,811 Warrants to purchase shares of Common Stock

This prospectus supplement No. 3 supplements and amends the prospectus dated June 20, 2018, as supplemented by prospectus supplement No.1, dated September 28, 2018, and prospectus supplement No. 2, dated October 5, 2018, related to the sale or other disposition from time to time of 388,403 shares of common stock, par value $0.00001 per share (the "Common Stock"), of InVivo Therapeutics Holdings Corp., a Nevada corporation (the "Company," "we," "us" or "our"), together with up to 388,403 warrants to purchase shares of Common Stock, and 6,242,811 pre-funded warrants to purchase shares of Common Stock together with 6,242,811 warrants to purchase shares of Common Stock, issued to Ladenburg Thalmann & Co. Inc., the underwriter named in the prospectus, also referred to as LTCO, pursuant to an underwriting agreement dated June 21, 2018 that we entered into with LTCO.

This prospectus supplement should be read in conjunction with the prospectus dated June 20, 2018, which is to be delivered with this prospectus supplement. This prospectus supplement is qualified by reference to the prospectus except to the extent that the information in this prospectus supplement supersedes the information contained in the prospectus. This prospectus supplement is not complete without, and may not be delivered or utilized except in connection with, the prospectus, including any amendments or supplements to it.

Our common stock is quoted on The Nasdaq Capital Market under the symbol "NVIV." On November 7, 2018, the last reported sale price of our common stock on The Nasdaq Capital Market was $2.05 per share.

This prospectus supplement incorporates into our prospectus the information contained in our Quarterly Report on Form 10 Q for the quarter ended September 30, 2018 filed with the Securities and Exchange Commission on November 8, 2018 and attached hereto.

Investing in our common stock involves risks. See "Risk Factors" beginning on page 10 of the prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the prospectus to which it relates are truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus supplement is November 8, 2018.

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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 September 30, 2018

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 if any, every Interactive Data File required to be submitted 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 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	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 November 1, 2018, 9,306,255 shares of the registrant's common stock, $0.00001 par value, were issued and outstanding.

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INVIVO THERAPEUTICS HOLDINGS CORP.

Quarterly Report on Form 10-Q for the Quarter Ended September 30, 2018

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PART I — FINANCIAL INFORMATION

SPECIAL NOTE

All share number and share prices presented in this Quarterly Report on Form 10-Q have been adjusted to reflect the 1-for-25 reverse stock split of InVivo Therapeutics Holdings Corp.'s common stock effected on April 16, 2018.

Item 1.Financial Statements.

InVivo Therapeutics Holdings Corp.

Consolidated Balance Sheets

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

(Unaudited)

	As of September 30, 2018	December 31, 2017
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 19,707	$ 12,910
Restricted cash	4	361
Prepaid expenses and other current assets	637	535
Total current assets	20,348	13,806
Property, equipment and leasehold improvements, net	112	157
Restricted cash	90	—
Other assets	926	82
Total assets	$ 21,476	$ 14,045
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 1,279	$ 988
Loan payable, current portion	216	452
Derivative warrant liability	—	4
Deferred rent, current portion	—	30

Accrued expenses	1,443	1,638
Total current liabilities	2,938	3,112
Loan payable, net of current portion	—	400
Deferred rent, net of current portion	—	367
Other liabilities	56	56
Total liabilities	2,994	3,935
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, $0.00001 par value, authorized 25,000,000 shares; 8,506,946 shares issued and outstanding at September 30, 2018; 1,370,992 shares issued and outstanding at December 31, 2017	1	1
Additional paid-in capital	223,286	194,016
Accumulated deficit	(204,805)	(183,907)
Total stockholders' equity	18,482	10,110
Total liabilities and stockholders' equity	$ 21,476	$ 14,045

See notes to the unaudited consolidated financial statements.

(Reflects 1-for-25 reverse stock split effective April 16, 2018)

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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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$ 928	$ 2,928	$ 3,352	$ 9,522
General and administrative	1,185	3,388	6,405	10,389
Total operating expenses	2,113	6,316	9,757	19,911
Operating loss	(2,113)	(6,316)	(9,757)	(19,911)
Other income (expense):				
Interest income / (expense), net	71	25	122	94
Other income / (expense), net	834	—	902	—
Derivatives gain (loss)	(1,967)	(3,059)	(12,165)	(2,264)
Other income (expense), net	(1,062)	(3,034)	(11,141)	(2,170)
Net loss	$ (3,175)	$ (9,350)	$ (20,898)	$ (22,081)
Net loss per share, basic and diluted	$ (0.42)	$ (6.99)	$ (5.81)	$ (16.98)
Weighted average number of common shares outstanding, basic and diluted	7,562,807	1,337,800	3,597,460	1,300,648
Other comprehensive loss:				
Net loss	(3,175)	(9,350)	(20,898)	(22,081)
Other comprehensive loss:				
Unrealized gain (loss) on marketable securities	—	—	—	—
Comprehensive loss	$ (3,175)	$ (9,350)	(20,898)	$ (22,081)

See notes to the unaudited consolidated financial statements.

(Reflects 1-for-25 reverse stock split effective April 16, 2018)

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InVivo Therapeutics Holdings Corp.

Consolidated Statements of Changes in Stockholders' Equity

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

(Unaudited)

	Three-Month Period Ended September 30, 2018				
	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance as of June 30, 2018	4,077,667	$ 1	$ 199,720	$ (201,630)	$ (1,909)
Share-based compensation expense	—	—	85		85
Fair value of derivative warrant liability reclassified to additional paid-in capital	—	—	23,436		23,436
Issuance of common stock upon vesting of restricted stock units	1,250	—	—		—
Issuance of common stock upon exercise of warrants	4,427,084	—	44		44
Issuance of common stock under ESPP	945	—	1		1
Net loss	—	—	—	(3,175)	(3,175)
Balance at September 30, 2018	8,506,946	$ 1	$ 223,286	$ (204,805)	$ 18,482

	Nine-Month Period Ended September 30, 2018				
	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance as of December 31, 2017	1,370,992	$ 1	$ 194,016	$ (183,907)	$ 10,110
Share-based compensation expense	—	—	541		541
Fair value of derivative warrant liability reclassified to additional paid-in capital	—	—	25,326		25,326

Issuance of common stock upon vesting of restricted stock units	1,250	—	—		—
Issuance of common stock upon exercise of warrants	5,478,002	—	55		55
Issuance of common stock under ESPP	1,133	—	4		4
Fractional shares issued due to reverse stock split	2,733	—	—		—
Issuance of common stock to 401(k) plan	440	—	6		6
Issuance of common stock in public offering	1,652,396	—	3,338		3,338
Net loss	—	—	—	(20,898)	(20,898)
Balance at September 30, 2018	8,506,946	$ 1	$ 223,286	$ (204,805)	$ 18,482

See notes to the unaudited consolidated financial statements.

(Reflects 1-for-25 reverse stock split effective April 16, 2018)

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InVivo Therapeutics Holdings Corp.

Consolidated Statements of Changes in Stockholders' Equity

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

(Unaudited)

	Three-Month Period Ended September 30, 2017				
	Common Stock		Additional Paid-in		Total Stockholders'
	Shares	Amount	Capital	Accumulated Deficit	Equity
Balance as of June 30, 2017	1,287,007	$ 1	$ 188,862	$ (169,893)	$ 18,970
Share-based compensation expense	—	—	1,031		1,031
Issuance of common stock on warrant exchange	80,857	—	3,537		3,537
Issuance of common stock under ESPP	391	—	22		22
Issuance of common stock to 401(k) plan	1,129	—	41		41
Net loss	—	—	—	(9,350)	(9,350)
Balance at September 30, 2017	1,369,384	$ 1	$ 193,493	$ (179,243)	$ 14,251

	Nine-Month Period Ended September 30, 2017				
	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance as of December 31, 2016	1,281,763	$ 1	$ 185,955	$ (157,007)	$ 28,949
Cumulative adjustment on adoption of ASU 2016-09	—	—	155	(155)	—
Share-based compensation expense	—	—	3,614		3,614
Issuance of common stock on warrant exchange	80,857	—	3,537		3,537
Issuance of common stock for services	14	—	—		—
Issuance of common stock under ESPP	710	—	51		51
Issuance of common stock upon exercise of stock options	3,576	—	26		26
	2,464	—	155		155

Issuance of common stock to 401(k) plan					
Net loss	—	—	—	(22,081)	(22,081)
Balance at September 30, 2017	1,369,384	$ 1	$ 193,493	$ (179,243)	$ 14,251

See notes to the unaudited consolidated financial statements.

(Reflects 1-for-25 reverse stock split effective April 16, 2018)

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InVivo Therapeutics Holdings Corp.

Consolidated Statements of Cash Flows

(In thousands)

(Unaudited)

	Nine Months Ended	
	2018	2017
Cash flows from operating activities:		
Net loss	$ (20,898)	$ (22,081)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	75	387
Loss on impairment of fixed assets	48	—
Derivatives loss	12,165	2,264
Non-cash interest expense	2	2
Common stock issued to 401(k) plan	6	154
Gain on lease assignment	(603)	—
Share-based compensation expense	541	3,614
Non-cash investment (income) expense, net	—	(2)
Changes in operating assets and liabilities:		
Prepaid expenses	(101)	(24)
Other assets	(860)	6
Accounts payable	291	259
Accrued expenses and other liabilities	9	(161)
Net cash used in operating activities	(9,325)	(15,582)
Cash flows from investing activities:		
Purchases of marketable securities	—	(8,256)
Sales of marketable securities	—	19,100
Purchases of property and equipment	(65)	(54)
Net cash (used in) provided by investing activities	(65)	10,790
Cash flows from financing activities:		
Proceeds from exercise of stock options	—	26
Proceeds from issuance of stock under ESPP	4	51
Proceeds from exercise of warrants	55	—
Repayment of loan payable	(636)	(315)
Repurchase of warrants	(14)	—
Proceeds from issuance of common stock and warrants, net of commissions and issuance costs	16,511	—

Net cash (used in) provided by financing activities	15,920	(238)
Increase (decrease) in cash and cash equivalents and restricted cash	6,530	(5,030)
Cash, cash equivalents and restricted cash at beginning of period	13,271	21,825
Cash, cash equivalents and restricted cash at end of period	$ 19,801	$ 16,795
Supplemental disclosure of cash flow information and non-cash investing and financing activities:		
Cash paid for interest	$ 35	$ 56
Non-cash issuance of common stock for warrants	$ 287	$ 3,537
Reclassification of derivative warrant liability to additional paid-in capital	$ 25,326	$ —

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 September 30, 2018 (Unaudited)

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

Business

InVivo Therapeutics Holdings Corp. (the "Company") is a pioneering biomaterials and biotechnology company with a focus on the treatment of spinal cord injuries ("SCIs"). The Company's Neuro-Spinal Scaffold™ implant is a bioresorbable polymer scaffold that is designed for implantation at the site of injury within the spinal cord to treat SCI. The proprietary technologies incorporate intellectual property that is licensed under an 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 September 30, 2018, the Company had consolidated cash and cash equivalents of $19.7 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 financing closed in June 2018 (see Note 9) provided necessary funding to fund operations for at least the next twelve months. The Company expects that it will need 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, pursuit of regulatory approvals, acquisition of capital equipment, laboratory and office facilities, establishment of production capabilities, for selling, general and administrative expenses, and other working capital requirements in the future 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 license arrangements.

Reverse Stock Split

On April 16, 2018, the Company effected a reverse stock split of its common stock, par value $0.00001 per share, at a ratio of 1-for-25. As a result of the reverse stock split, (i) every 25 shares of the issued and outstanding common stock were automatically converted into one newly issued and outstanding share of common stock, without any change in the par value per share; (ii) shares of common stock underlying outstanding stock options and other equity instruments

convertible into common stock were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities, and (iii) the number of authorized shares of common stock outstanding was proportionally decreased.

All of the Company's historical share and per share information related to issued and outstanding common stock and outstanding options and warrants exercisable for common stock in these financial statements have been adjusted, on a retroactive basis, to reflect this 1-for-25 reverse stock split.

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, 2017 included in the Company's Annual Report on Form 10-K as filed with the United States Securities and Exchange Commission ("SEC") on March 12, 2018. The unaudited consolidated financial statements reflect all adjustments, consisting only of normal recurring adjustments, which are, in the opinion of management, necessary for a fair presentation of the Company's financial position as of September 30, 2018 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

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InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements for the Quarter Ended September 30, 2018 (Unaudited)

(Continued)

rules and regulations; however, the Company believes that its disclosures are adequate to ensure that the information presented is not misleading.

Recently Adopted Accounting Standards

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 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. Collectively, these standards are effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within each annual reporting period. Currently, this guidance is not applicable to the Company as the Company does not generate revenue. However, the Company will adopt and evaluate the impact of adopting these standards on its consolidated financial statements when the Company begins to generate revenue.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments - Overall (Subtopic 825-10) - Recognition and Measurement of Financial Assets and Financial Liabilities ("ASU 2016-01"). ASU 2016-01 is intended to improve the recognition and measurement of financial instruments by; requiring equity investments to be measured at fair value with changes in fair value recognized in net income: requiring public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requiring separate presentation of financial assets and financial liabilities by measurement category and form of financial asset on the balance sheet or the accompanying notes to the financial statements; eliminating the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured and amortized at cost on the balance sheet; and requiring a reporting organization to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the organization has elected to measure the liability at fair value in accordance with the fair value option for financial instruments. ASU 2016-01 is effective for annual periods and

interim periods within those annual periods, beginning after December 15, 2017. The amendments should be applied by means of a cumulative-effect adjustment to the balance sheet as of the beginning of the fiscal year of adoption. The amendments related to equity securities without readily determinable fair values (including disclosure requirements) should be applied prospectively to equity investments that exist as of the date of adoption. In February 2018, the FASB issued ASU No. 2018-03 which includes technical corrections and improvements to clarify the guidance in ASU No. 2016-01. The Company adopted ASU 2016-01 on January 1, 2018 and it did not have any impact on its accounting for equity investments, fair value disclosures or other disclosure requirements.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments ("ASU No. 2016-15"), which clarifies the classification of certain cash receipts and cash payments in the statement of cash flows, including debt prepayment or extinguishment costs, settlement of contingent consideration arising from a business combination and insurance settlement proceeds. The Company adopted ASU 2016-15 on January 1, 2018, and it did not result in any changes to the presentation of amounts shown on the Company's consolidated statements of cash flows for all periods presented.

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InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements for the Quarter Ended September 30, 2018 (Unaudited)

(Continued)

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (A Consensus of the FASB Emerging Issues Task Force) ("ASU No 2016-18"). The amendments in this update require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company adopted ASU No. 2016-18 in the first quarter of 2018 and applied the guidance retrospectively to the prior period consolidated statement of cash flows. The following table provides a reconciliation of cash, cash equivalents, and restricted cash within the statement of financial position that sum to the total of the same such amounts shown in the statement of cash flows.

(In thousands)	September 30, 2018	September 30, 2017
Cash and cash equivalents	$ 19,707	$ 16,434
Restricted cash included in current assets	4	361
Restricted cash included in other non-current assets	90	—
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 19,801	$ 16,795

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 adopted ASU 2017-09 on January 1, 2018 and it did not have a material effect on the Company's financial position, results of operations or disclosures.

In December 2017, the SEC issued Staff Accounting Bulletin 118 ("SAB 118") to address the application of U.S. GAAP in situations in which a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Cuts and Jobs Act (the "Tax Reform Act") which was signed into law on December 22, 2017. In March 2018, the FASB issued ASU 2018-05, which amended ASC 740-Income Taxes, to incorporate the requirements of SAB 118. The Company recognized the provisional tax impacts of the Tax Reform Act in the fourth quarter 2017. During first quarter 2018, the Company did not receive any additional information regarding these provisional calculations. As a result, the Company continues to anticipate finalizing the Company's analysis in connection with the completion of its tax return

for 2017 to be filed in 2018.

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 gathering information and evaluating the impact of this guidance on our consolidated financial statements and related disclosures.

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

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InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements for the Quarter Ended September 30, 2018 (Unaudited)

(Continued)

periods beginning after December 15, 2018, including interim reporting periods within each annual reporting period. The Company has concluded that the adoption of ASU 2017-11 will not have a material impact on the financial statements.

In February 2018, the FASB issued Accounting Standards Update No. 2018-02, Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income. This update relates to the impacts of the tax legislation commonly referred to as the Tax Reform Act. The guidance permits the reclassification of certain income tax effects of the Tax Reform Act from other comprehensive income to retained earnings (stranded tax effects). The guidance also requires certain new disclosures. The guidance is effective for annual periods beginning after December 15, 2018, and interim periods within those reporting periods. Early adoption is permitted. Entities may adopt the guidance using one of two transition methods; retrospective to each period (or periods) in which the income tax effects of the Tax Reform Act related to the items remaining in other comprehensive income are recognized or at the beginning of the period of adoption. The Company is currently evaluating the impact that the guidance may have on its Consolidated Financial Statements.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective on November 5, 2018. The Company adopted this release in the third quarter of 2018.

2.CASH AND CASH EQUIVALENTS

At September 30, 2018 and December 31, 2017, cash equivalents were comprised of money market funds and other short-term investments.

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

Cash and cash equivalents consisted of the following:

(In thousands)	September 30, 2018	December 31, 2017
Cash	$ (156)	$ 23
Money market funds	19,863	12,887
Total cash and cash equivalents	$ 19,707	$ 12,910

3.RESTRICTED CASH

Restricted cash as of September 30, 2018 and December 31, 2017 was $94 thousand and $361 thousand, respectively. Restricted cash as of September 30, 2018 included a $50 thousand security deposit related to the

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InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements for the Quarter Ended September 30, 2018 (Unaudited)

(Continued)

Company's credit card account, $4 thousand related to 401(k) reserve account and a $40 thousand 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, and corporate obligations, in accordance with the Company's investment policy that primarily seeks to maintain adequate liquidity and preserve capital.

As of September 30, 2018, and December 31, 2017, the Company had no marketable securities.

5.FAIR VALUES 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.

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 September 30, 2018			
(In thousands)	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	$ 19,863	$ —	$ —	$ 19,863
Derivative warrant liability	$ —	$ —	$ —	$ —

	At December 31, 2017			
(In thousands)	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	$ 12,887	$ —	$ —	$ 12,887
Derivative warrant liability	$ —	$ 4	$ —	$ 4

6.COMMITMENTS AND CONTINGENCIES

Leases

On November 30, 2011, the Company entered into a commercial lease for 26,342 square feet of office, laboratory, and manufacturing space in Cambridge, Massachusetts (as amended on September 17, 2012 and October 31, 2017,

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the “Cambridge Lease”). The term of the Cambridge Lease was six years and three months, with one five-year extension option. On August 21, 2017, the Company exercised its option for the five-year extension on the Cambridge Lease. The five-year renewal lease term was set to commence on November 1, 2018 and end on October 31, 2023. The terms of the Cambridge Lease required a standby letter of credit in the amount of $311 thousand.

On March 31, 2016, the Company entered into a short-term lease, to sub-lease 5,233 square feet of its facility (the “2016 Sublease”). The 2016 Sublease term was from April 1, 2016 through January 31, 2017. In connection with the 2016 Sublease, the Company received sublease income for the three and nine months ended September 30, 2017 of $26 thousand, which was recorded as an offset to rent expense.

On June 13, 2017, the Company entered into a new short-term lease, to sub-lease 5,233 square feet of its facility (the “Moderna Sublease”). The lease term was from July 1, 2017 through October 26, 2018. On June 19, 2017, the Company received a $55 thousand security deposit under the terms of the Moderna Sublease. In conjunction with the assignment of the Cambridge Lease on May 3, 2018 further described below, this security deposit was transferred to the third party that assumed the lease. In connection with Moderna Sublease, the Company did not record any sublease income for the three-month period ended September 30, 2018. In connection with the Moderna Sublease, the Company received sublease income of $112 thousand for the nine-month period ended September 30, 2018, which was recorded as an offset to rent expense.

On May 3, 2018, the Company assigned the Cambridge Lease to a third party who assumed all of the Company’s remaining rights and obligations under the Cambridge Lease including the Moderna Sublease. On the same date as the lease assignment, the Company entered into a sublease for 5,104 square feet of space, originally part of the Cambridge Lease, from the third party to which the Company assigned the Cambridge Lease. The sublease commenced on May 3, 2018 through October 31, 2023 and contains rent holiday and rent escalation clauses. In connection with the lease assignment and the sublease, the $311 thousand standby letter of credit was terminated, and a new standby letter of credit was established for $40 thousand. On November 1, 2018, the standby letter of credit will be increased to $60 thousand. The $55 thousand security deposit under the Moderna Sublease was transferred to the third party and $603 thousand of deferred rent was removed from the consolidated balance sheets as of June 30, 2018. The resulting gain was recorded within the consolidated statement of operations and comprehensive loss during the second quarter of 2018. The Company also wrote off certain furniture, fixtures and equipment (including laboratory equipment) and recorded an impairment charge of $48 thousand for the nine months ended September 30, 2018. The Company did not record any impairment charges for the three-month period ended September 30, 2018.

The Company recognizes rent expense on a straight-line basis over the term of the lease and records the difference between the amount charged to expense and the rent paid as prepaid rent or deferred rent liability. As of September 30, 2018, and December 31, 2017, the amount of prepaid rent was $108 thousand and $0, respectively. As of September 30, 2018, and December 31, 2017, the amount of deferred rent liability was $0 and $397 thousand, respectively.

Pursuant to the terms of the non-cancelable lease and sublease agreements in effect at September 30, 2018, the future minimum rent commitments are as follows (in thousands):

Year Ended December 31,	
Fourth Quarter 2018	—
2019	243
2020	375
2021	386
2022	398
Thereafter	339
Total	$ 1,741

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Total rent expense for the three-month period ended September 30, 2018 was $107 thousand. Total rent expense for the three-month period ended September 30, 2017 was $269 thousand.

Total rent expense for the nine-month period ended September 30, 2018 was $746 thousand, and does not include the one-time gain on termination of the Cambridge Lease of $603 thousand that was recorded to the consolidated statement of operations and comprehensive loss during the second quarter of 2018. Total rent expense for the nine-month period ended September 30, 2017 was $828 thousand.

Compensation Commitment

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 was earned over a period of one year. The expense related to the compensation arrangement was $87 thousand and $174 thousand for the three-month and nine-month periods ended September 30, 2017, respectively. As of September 30, 2018, there were no outstanding payments to the executive.

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 thousand 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 denying that Mr. Reynolds is entitled to any relief. The parties have completed discovery. On March 3, 2017, the counterclaim defendants filed a motion for summary judgement on all counterclaims asserted by Mr. Reynolds. On October 18, 2017, the Court allowed the motion for summary judgment in substantial part, and denied it in part. The Court, citing disputed issues of fact, declined to dismiss the counterclaims for breach of contract, breach of implied covenant of good faith and fair dealing, and declaratory judgment concerning Mr. Reynolds' attempted exercise of certain stock options, which Mr. Reynolds claims is the equivalent of 47,864 shares of common stock, but dismissed all other claims asserted by Mr. Reynolds. In July 2018, the parties reported the case as settled to the Court.

Vendor Dispute

In July 2018, the Company entered into a settlement agreement with a former vendor under which the vendor agreed to pay the Company $1.2 million, of which $800 thousand was received in July 2018 and is included in other income on the statement of operations and other comprehensive loss. The remaining $400 thousand is owed to the Company by December 1, 2018.

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7. ACCRUED EXPENSES

Accrued expenses consisted of the following:

(In thousands)	September 30, 2018	December 31, 2017
Severance and restructuring	$ 917	$ 1,160
Bonus	238	62
Vacation	53	55
Payroll	40	79
Other accrued expenses	195	282
Total accrued expenses	$ 1,443	$ 1,638

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 thousand 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 in March 2019. Commencing on May 1, 2015, equal monthly payments of $41 thousand are due until loan maturity.

In May 2018, in order to obtain the consent of MassDev for facility changes, including the assignment of the Cambridge Lease, and the sale of certain assets, the Company paid down $300 thousand of principal on the MassDev loan. As of September 30, 2018, $216 thousand in principal payments will be due in the next twelve months. In October 2012, as part of the agreement, the Company issued MassDev a warrant for the purchase of 362 shares of the Company's common stock. The warrant has a seven-year term and is exercisable at $166 per share. The fair value of the warrant was determined to be $32 thousand and is being amortized through interest expense over the life of the

note. Amortization expense was $1 thousand in each of the three-month periods ended September 30, 2018 and 2017 and $3 thousand in each of the nine-month periods ended September 30, 2018 and 2017. 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 September 30, 2018 and 2017 was $9 thousand and $17 thousand, respectively. Interest expense related to this loan for the nine-month periods ended September 30, 2018 and 2017 was $35 thousand, and $56 thousand respectively.

9.COMMON STOCK

In May 2018, the Company's stockholders approved an amendment to the Company's Articles of Incorporation to increase the number of shares of authorized common stock from 4,000,000 to 25,000,000 shares. As of September 30, 2018, and December 31, 2017, 8,506,946 and 1,370,992 shares were issued and outstanding respectively.

In June 2018, the Company closed an underwritten public offering of an aggregate of 1,378,400 Common Units, at an offering price of $2.00 each, each comprised of one share of the Company's common stock, par value $0.00001 per share and one Series A warrant to purchase one share of common stock. The public offering also included 6,242,811 pre-funded units at an offering price of $1.99 each, each comprised of one pre-funded Series B Warrant, and one Series A warrant to purchase one share of common stock. Each Series A warrant has an exercise price of $2.00 per share, is exercisable immediately and expires five years from the date of issuance. Each Series B warrant has an exercise price of $0.01 per share, is exercisable immediately and will expire twenty years from the date of issuance (see Note 12). The net proceeds to the Company, after deducting the underwriting discounts and

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commissions and other offering expenses, were $13.5 million (see Note 12). In September 2018, the Company entered into an Amendment to Warrant Agency Agreement and Warrants (the "Ladenburg Warrant Amendment") with Continental Stock Transfer & Trust Company ("Continental") that amends the Warrant Agency Agreement, by and between the Company and Continental, as Warrant Agent, dated June 25, 2018, and the Series A Common Stock Purchase Warrant, and the Series B Pre-Funded Common Stock Purchase Warrant both dated June 25, 2018 (the Series A and Series B Warrant, collectively the "2018 Warrants"). The Ladenburg Warrant Amendment adds a provision to each of the warrants that allows the Company or a successor entity whose stock is not listed on a trading market to, in connection with a Fundamental Transaction (as such term is defined in the 2018 Warrants) that is not within the Company's control, purchase the warrant from the holder, at the holder's option, by paying the same form of consideration in the same proportion that is offered to the holders of the Company's common stock in connection with the Fundamental Transaction, including cash, stock, any combination thereof and any choice of consideration thereof, in an amount equal to the Black-Sholes Value of the remaining unexercised portion of the Warrant on the consummation date of the Fundamental Transaction. The fair value of the amended 2018 Warrants was re-measured immediately prior to the date of the Ladenburg Warrant Amendment with changes in fair value recorded as a loss of $764 thousand in the Company's consolidated statement of operations and $14.7 million was reclassified to equity. During the three months ended September 30, 2018, the Company issued an aggregate of 4,427,084 shares of common stock upon the exercise of Series B warrants for aggregate proceeds of $44 thousand. The Company reclassified $8.7 million from derivative warrant liability to additional paid-in capital and recorded a derivative loss of $1.2 million in connection with the warrant exercises. During the nine months ended September 30, 2018, the Company issued an aggregate of 5,478,002 shares of common stock upon the exercise of Series B warrants for aggregate proceeds of $55 thousand. The Company reclassified $10.6 million from derivative warrant liability to additional paid-in capital and recorded a derivative loss of $1.2 million in connection with the warrant exercises.

In January 2018, the Company entered into a purchase and a registration rights agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"), under which it has the right to sell up to $15 million, in shares of our common stock, $0.00001 par value per share, to Lincoln Park over a twenty-four-month period, subject to certain limitations and conditions set forth in the purchase agreement and registration rights agreement. On May 30, 2018 the Company's stockholders approved to increase the issuance and sale by the Company to Lincoln Park, including the Company's prior issuances and sales of shares of common stock to Lincoln Park since January 2018, of up to 1,200,000 shares of common stock. In accordance with the terms of the purchase agreement, at the time the Company signed the purchase agreement and the registration rights agreement, it issued 17,192 shares to Lincoln Park as consideration for its commitment to purchase shares of the Company's common stock under the purchase agreement and recorded $627 thousand in deferred offering costs. As of September 30, 2018, these costs were reclassified to additional paid-in capital. During the three months ended September 30, 2018, the Company did not sell any shares to Lincoln Park. During the nine months ended September 30, 2018, the Company sold an aggregate of 256,804 shares to Lincoln Park, for aggregate proceeds of $3.1 million net of issuance costs.

In May 2018, the Company's Board of Directors approved to increase the number of shares of Common Stock reserved under the 401(k) Plan by 4,000 shares, bringing the aggregate number of shares of Common Stock eligible for distribution pursuant to the 401(k) Plan as of that date to 4,100 shares. In the second quarter of 2018 the Company revised its 401(k)-matching policy to move from share matching to cash-based matching. During the nine months ended September 30, 2018, the Company issued an aggregate of 440 shares of common stock with a fair value of $6 thousand to the Company's 401(k) plan as a matching contribution. The Company contributed $32 thousand in matching contributions to employee 401(k) accounts during the nine months ended September 30, 2018. During the year ended December 31, 2017, the Company issued an aggregate of 3,933 shares of common stock with a fair value of $183 thousand to the Company's 401(k) plan as a matching contribution.

During the nine months ended September 30, 2018, the Company issued an aggregate of 1,133 shares of common stock under the Company's Employee Stock Purchase Plan (the "ESPP") and received cash proceeds of approximately $4 thousand. During the year ended December 31, 2017, the Company issued an aggregate of 710 shares of common stock under the ESPP and received cash proceeds of $51 thousand.

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During the year ended December 31, 2017, the Company issued an aggregate of 3,576 shares of common stock upon the exercise of stock options and received cash proceeds from such exercises of $26 thousand.

During the year ended December 31, 2017, the Company issued an aggregate of 139 shares of common stock upon the exercise of warrants and received cash proceeds from such exercises of $3 thousand.

During the year ended December 31, 2017, the Company issued an aggregate of 80,857 shares of common stock to certain holders of warrants, dated May 9, 2014, in exchange for their warrants to purchase an aggregate of 23,102 shares of common stock. The Company did not receive any cash proceeds from the warrant exchanges.

10.STOCK-BASED COMPENSATION

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”). The 2007 Plan provided that the Company’s Board of Directors (or committees and/or executive officers delegated by the Board of Directors) could 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.

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. As of September 30, 2018, the total number of shares available to be issued under the 2015 Plan was 201,011 shares, consisting of 160,000 shares initially authorized under the 2015 Plan shares plus the 12,894 shares that remained available for grant under the 2010 Plan at the time of its termination adjusted for cumulative cancellations, forfeitures and issuances from the 2010 Plan and 2015 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.

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 7,500 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) 2,000 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 50,000 shares. As of December 31, 2017, there were 9,933 shares reserved for issuance under the ESPP.

In January 2018, 188 shares that were purchased in the offering period commencing on July 1, 2017 and ending on December 31, 2017 were issued under the ESPP. In July 2018, 945 shares that were purchased in the offering period commencing on January 1, 2018 and ending on June 30, 2018 were issued under the ESPP. As of September 30, 2018, $1 thousand of employee payroll deductions had been withheld since July 1, 2018, the commencement of the current offering period, and are included in accrued expenses on the balance sheet. The

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ESPP is considered a compensatory plan with the related compensation cost recognized over each six-month offering period. The compensation expense related to the ESPP for the three-month periods ended September 30, 2018 and 2017 was $1 thousand and $3 thousand, respectively, and is included in share-based compensation expense. The compensation expense related to the ESPP for the nine-month periods ended September 30, 2018 and 2017 was $1 thousand and $16 thousand, respectively, and is included in share-based compensation expense

Stock-based compensation

For the three-month periods ended September 30, 2018 and 2017, the Company recorded stock-based compensation expense of $85 thousand and $1 million, respectively, inclusive of the expense related to the ESPP. For the nine-month periods ended September 30, 2018 and 2017, the Company recorded stock-based compensation expense of $541 thousand and $3.6 million, respectively, inclusive of the expense related to the ESPP. Stock-based compensation expense for the nine-month period ended September 30, 2017 included $24 thousand of expense related to a stock option modification.

The Company adopted ASU 2016-09 on January 1, 2017. Prior to the adoption of this standard, the Company recognized stock-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 stock-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 thousand 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 expected term of options granted under the Plans, all of which qualify as “plain vanilla,” is based on the average of the contractual term (10 years) and the vesting period (generally, 48 months). For non-employee options, the expected term is the contractual term. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option.

The assumptions used principally in determining the fair value of options granted were as follows:

	September 30, 2018	December 31, 2017
Risk-free interest rate	2.45%	1.69 - 2.36%
Expected dividend yield	0%	0%
Expected term (employee grants)	5.27 Years	6.22 Years
Expected volatility	96.07%	104%

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Stock options

A summary of option activity as of September 30, 2018 and changes for the nine-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, 2017	134,770	$ 164.29		
Granted	3,024	$ 17.25		
Expired	(5,334)	$ 173.13		
Cancelled/Forfeited	(90,070)	$ 175.07		
Exercised	—	$ —		
Outstanding at September 30, 2018	42,390	$ 129.89	6.80	$ —
Vested at September 30, 2018	30,667	$ 153.41	6.08	$ —

The weighted average grant-date fair value of options granted during the nine months ended September 30, 2018 was $12.88 per share. The total fair value of options that vested in the three months ended September 30, 2018 was $96 thousand. The total fair value of options that vested in the nine months ended September 30, 2018 was $899 thousand. For the three-month period ended September 30, 2018, the Company recorded stock-based compensation expense of $58 thousand related to stock options. For the nine-month period ended September 30, 2018, the Company recorded stock-based compensation expense of $477 thousand related to stock options. As of September 30, 2018, total unrecognized compensation expense related to non-vested share-based option compensation arrangements amounted to $283 thousand and is estimated to be recognized over a period of 2.08 years.

Restricted Stock Units

The following table summarizes the restricted stock unit (“RSU”) activity under the 2015 Plan during the nine-month period ended September 30, 2018:

	Number of Grants	Weighted-Average Grant Date Fair Value
Unvested balance at December 31, 2017	20,000	$ 25.70
Granted	—	—
Vested/Released	(1,250)	$ 31.25
Forfeited	(5,500)	$ 31.25
Unvested balance at September 30, 2018	13,250	$ 22.87

For the three-month period ended September 30, 2018, the Company recorded stock-based compensation expense of $26 thousand related to the time-based RSUs. For the nine-month period ended September 30, 2018, the Company recorded stock-based compensation expense of $61 thousand related to the time-based RSUs. As of September 30, 2018, total unrecognized compensation expense related to non-vested RSUs amounted to $249 thousand which the Company expects to recognize over a remaining weighted-average of 2.88 years.

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11. WARRANTS

The following table presents information about warrants to purchase common stock issued and outstanding at September 30, 2018:

Year Issued	Classification	Number of Warrants	Exercise Price	Date of Expiration
2012	Equity	243	$ 166.00	10/5/2019
2014	Equity	307	$ 11.75	5/9/2021
2016	Equity	85,869	$ 250.00	3/18/2021
2018	Equity	7,621,211	$ 2.00	6/25/2023
2018	Equity	764,809	$ 0.01	6/25/2038
Total		8,472,439		
Weighted average exercise price			$ 4.34	
Weighted average life in years				6.07

In June 2018, the Company closed an underwritten public offering of an aggregate of 1,378,400 Common Units, at an offering price of $2.00 each, each comprised of one share of the Company’s common stock, par value $0.00001 per share and one Series A warrant to purchase one share of common stock. The public offering also included 6,242,811 pre-funded units at an offering price of $1.99 each, each comprised of one pre-funded Series B Warrant, and one Series A warrant to purchase one share of common stock. Each Series A warrant has an exercise price of $2.00 per share, is exercisable immediately and expires five years from the date of issuance. Each Series B warrant has an exercise price of $0.01 per share, is exercisable immediately and will expire twenty years from the date of issuance (see Note 12). The net proceeds to the Company, after deducting the underwriting discounts and commissions and other offering expenses, were $13.5 million.

At inception the 2014 and 2018 Warrants had provisions that precluded equity classification. Upon amendment, the Company assessed whether the warrants required accounting as derivatives and 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. See below for a further description of the warrant amendment.

Warrant Exchange

On August 10, 2017, the Company entered into exchange agreements with certain holders of the warrants, dated May 9, 2014, to exchange such warrants for shares of common stock equivalent to 3.5 times the number of shares of common stock issuable to such holders at the $96.75 exercise price under the warrants as of the date of the exchanges. The Company issued an aggregate of 80,857 shares of common stock to the warrant holders in exchange for their warrants to purchase an aggregate of 23,102 shares of common stock. The warrants exchanged in this transaction were subsequently cancelled and terminated.

The Company re-measured the fair value of the exchanged warrants immediately prior to the exchange and recorded a $3.0 million derivatives loss on the statement of operations and a corresponding increase to the warrant liability on the balance sheet. The fair value of the warrants immediately prior to the exchange was equivalent to 80,857 shares of common stock at the Company's closing stock price of $43.75 on August 9, 2017, the day before execution of the exchange. As a result of the exchange, the Company recorded the settlement by removing the derivative liability related to the exchanged warrants and recorded the issuance of common stock for $3.5 million.

Following the warrant exchange, there were additional warrants, dated May 9, 2014, to purchase shares of common stock that remain outstanding ("Outstanding 2014 Warrants"). As a result of the Company's issuance of common stock in exchange for certain of the liability warrants, the exercise price of the Outstanding 2014

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Warrants was adjusted downwards from $96.75 per share to $20.75 per share and additional warrants were issued such that the Outstanding 2014 Warrants were exercisable for an aggregate of 1,941 shares of common stock.

Warrant Cancellation

In the fourth quarter of 2017, the Company entered into warrant cancellation agreements with certain holders of the Outstanding 2014 Warrants to cancel and terminate such warrants for total cash consideration of $40 thousand. As of December 31, 2017, the remaining Outstanding 2014 Warrants were exercisable for an aggregate of 537 shares of common stock.

During nine months ended September 30, 2018 the Company entered into warrant cancellation agreements with certain holders of the Outstanding 2014 Warrants to cancel and terminate such warrants for total cash consideration of $14 thousand. As of September 30, 2018, the sole remaining Outstanding 2014 Warrants was exercisable for an aggregate of 307 shares of common stock.

Warrant Amendment

In May 2018, the Company entered into a warrant amendment agreement with the sole remaining holder of an Outstanding 2014 Warrant (the “Warrant Amendment”). The warrant holder received cash compensation of $19 thousand and a two year extension of warrant term in exchange for the removal of all anti-dilution provisions except those for stock splits, reverse splits or stock dividends. As a result of the amendment, the Company reclassified the remaining 2014 warrants valued at $1 thousand to stockholders’ equity (see Note 12).

In September 2018, the Company entered into the Ladenburg Warrant Amendment. As a result of the Ladenburg Warrant Amendment, the Company reclassified the 2018 Warrants valued at $14.7 million to stockholders’ equity (see Note 12).

12. DERIVATIVE INSTRUMENTS

The warrants issued in connection with the Company's 2018 underwritten public offering had provisions that precluded the Company from classifying them as equity instruments (See Note 11). Accordingly, these warrants had been accounted for as derivative warrant liabilities. The Company used the Black-Scholes model and assumptions that considered, 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 these warrants.

At inception the fair value of the Series B pre-funded warrants was estimated at $11.5 million using a Black-Scholes model with the following assumptions: expected volatility of 202.51%, risk free interest rate of 2.95%, expected life of 20 years and no dividends.

At inception the fair value of the Series A warrants was estimated at $13.7 million using a Black-Scholes model with the following assumptions: expected volatility of 202.51%, risk free interest rate of 2.75%, expected life of 5 years and no dividends.

The Company allocated $13.2 million of the net proceeds to record the relative fair value of the warrant liability, with the remaining amount of $286 thousand recorded to permanent equity. The Company subsequently recorded the fair value of the warrant liability at $25.2 million with the loss of $12 million being recorded as a derivative loss on the Company's consolidated statement of operations and comprehensive loss during the second quarter of 2018.

In September 2018, the Company entered into the Ladenburg Warrant Amendment. The fair value of the amended 2018 Warrants was re-measured immediately prior to the date of the Ladenburg Warrant Amendment with

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InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements for the Quarter Ended September 30, 2018 (Unaudited)

(Continued)

changes in fair value recorded as a loss of $764 thousand in the Company's consolidated statement of operations and $14.7 million was reclassified to equity.

During the three months ended September 30, 2018, the Company issued an aggregate of 4,427,084 shares of common stock upon the exercise of Series B warrants for aggregate proceeds of $44 thousand. The Company reclassified $8.7 million from derivative warrant liability to additional paid-in capital and recorded a derivative loss of $1.2 million in connection with the warrant exercises. During the nine months ended September 30, 2018, the Company issued an aggregate of 5,478,002 shares of common stock upon the exercise of Series B warrants for aggregate proceeds of $55 thousand. The Company reclassified $10.6 million from derivative warrant liability to additional paid-in capital and recorded a derivative loss of $1.2 million in connection with the warrant exercises.

The 2014 Warrants issued in connection with the Company's May 2014 public offering had anti-dilution protection provisions and, under certain conditions, required the Company to automatically reprice the 2014 Warrants (See Note 11). Accordingly, the 2014 Warrants had been accounted for as derivative warrant liabilities. Through the date of the warrant exchange (Note 11), the Company used the Binomial Lattice option pricing model and assumptions that considered, 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 2014 Warrants considered to be derivative instruments.

In May 2018, the Company entered into the Warrant Amendment, which removed provisions that had previously precluded equity classification treatment of the 2014 Warrants on the Company's balance sheets. The fair value of the amended 2014 Warrants was re-measured immediately prior to the date of amendment with changes in fair value recorded as a loss of $1 thousand in the Company's consolidated statement of operations and $1 thousand was reclassified to equity.

As of December 31, 2017, the derivative warrant liability was insignificant and was included as a derivative warrant liability in current liabilities on the balance sheet. Changes in the fair value of the derivative financial instruments were recognized in the Company's consolidated statement of operations as a derivative gain or loss.

The assumptions used principally in determining the fair value of the 2014 Warrants were as follows:

	2014 Warrants December 31, 2017	
Risk free interest rate	1.91	%
Expected dividend yield	—	%
Contractual term (in years)	1.4	
Expected volatility	82	%

The table below presents the changes in the derivative warrant liability during the three-month and nine-month periods ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30,	
	2018	2017
Balance at June 30,	$ 21,469	$ 519
Reduction in derivative liability due to exercise and repurchase of warrants	(8,730)	—
Reclassification of fair value of derivative liabilities to equity on amendment of warrant agreements	(14,706)	—
Increase in derivative liability prior to warrant exchange	—	3,029
Reduction in derivative liability due to warrant exchange	—	(3,537)
Increase in the fair value of warrants	1,967	30
Balance at September 30,	$ —	$ 41

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InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements for the Quarter Ended September 30, 2018 (Unaudited)

(Continued)

	Nine Months Ended September 30,	
	2018	2017
Balance at December 31,	$ 4	$ 1,314
Issuance of new warrants	13,172	—
Reduction in derivative liability due to exercise and repurchase of warrants	(10,634)	—
Reclassification of fair value of derivative liabilities to equity on amendment of warrant agreements	(14,707)	—
Increase in derivative liability prior to warrant exchange	—	3,029
Reduction in derivative liability due to warrant exchange	—	(3,537)
Increase (decrease) in the fair value of warrants	12,165	(765)
Balance at September 30,	$ —	$ 41

13. RESTRUCTURING

In August 2017, the Company implemented a strategic restructuring. In conjunction with the strategic restructuring, the Company completed a reduction in force eliminating approximately 39% of its workforce.

During the three and nine months ended September 30, 2017, the Company recorded $738 thousand in restructuring expenses, including employee severance benefits and related costs, as well as a write-off of certain fixed assets. The Company did not record any restructuring expenses during the three or nine months ended September 30, 2018.

The following table summarizes the restructuring costs by category for the periods indicated (in thousands):

	Three and Nine Months Ended September 30, 2017

	Cash	Non-Cash (1)	Total
Research and development	$ 602	$ 41	$ 643
General and administrative	95	—	95
	$ 697	$ 41	$ 738

(1) The non-cash restructuring expenses represent write-offs of certain fixed assets in connection with the restructuring. The write-offs were recorded as a charge to research and development expense on the statement of operations.

The following table summarizes the restructuring reserve for the periods indicated (in thousands):

	September 30, 2018	December 31, 2017
Restructuring reserve beginning balance	$ 348	$ —
Cash restructuring expenses incurred during the period	—	857
Amounts paid during the period	(348)	(509)
Restructuring reserve ending balance	$ —	$ 348

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InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements for the Quarter Ended September 30, 2018 (Unaudited)

(Continued)

14. 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 and June 2018 capital raises, unvested restricted stock units and convertible securities are anti-dilutive and therefore excluded from diluted loss per share calculations.

For the three-month and nine-month periods ended September 30, 2018 and 2017, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive:

	September 30,	
	2018	2017
Warrants	8,472,439	111,930
Stock options	42,390	158,920
Unvested restricted stock units	13,250	11,800
	8,528,079	282,650

15. SUBSEQUENT EVENTS

Subsequent to September 30, 2018 and as of November 5, 2018, the Company issued an aggregate of 799,309 shares of common stock upon the exercise of the warrants associated with the June 2018 underwritten public offering. Upon exercise, the Company received $77 thousand in cash.

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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, 2017 (the "2017 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.

All share amounts presented in this Item 2 give effect to the 1-for-25 reverse stock split of our outstanding shares of common stock that occurred on April 16, 2018.

Overview

We are a research and clinical-stage biomaterials and biotechnology company with a focus on treatment of spinal cord injuries, or SCIs. 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. The Neuro-Spinal Scaffold implant incorporates intellectual property licensed under an exclusive, worldwide license from Boston Children's Hospital and the Massachusetts Institute of Technology. We also plan to evaluate other technologies and therapeutics that may be complementary to our development of the Neuro-Spinal Scaffold implant or offer the potential to bring us closer to our goal of redefining the life of the SCI patient.

The current standard of care for acute management of spinal cord injuries focuses on preventing further injury to the spinal cord. However, the current standard of care does not address repair of the spinal cord.

Our Clinical Program

We currently have one clinical development program for the treatment of acute SCI.

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Neuro-Spinal Scaffold Implant for acute SCI

Our Neuro-Spinal Scaffold implant is an investigational bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord. The Neuro-Spinal Scaffold implant 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 implant 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 implant; 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 implant by multiple combination strategies involving electrostimulation devices, additional biomaterials, drugs approved by the U.S. Food and Drug Administration, or FDA, or growth factors. We expect the Neuro-Spinal Scaffold implant to be regulated by the FDA as a Class III medical device.

Completed Pilot Study

We conducted an early feasibility human pilot study, as the initial phase of a larger pivotal study, of our Neuro-Spinal Scaffold under our approved Investigational Device Exemption, or IDE, application for the treatment of complete, traumatic acute SCI. The study was intended to assess the safety and feasibility of the Neuro-Spinal Scaffold for the treatment of complete thoracic functional SCI, as well as to gather preliminary evidence of the clinical effectiveness of the Neuro-Spinal Scaffold.

The pilot study was initially approved for five subjects in up to six clinical sites across the United States, and was later modified to increase the number of allowable clinical sites to up to 20 and to permit enrollment of up to 10 subjects. The pilot study was initially staggered such that each patient that met the eligibility criteria would be followed for three months prior to enrolling the next patient in the study. In December 2014, the FDA approved an expedited enrollment plan that allowed us to continue enrolling patients more rapidly barring any significant safety issues. We enrolled five subjects in the pilot study between October 2014 and September 2015. The FDA approved conversion of this pilot study to a pivotal probable benefit study, which we refer to as The INSPIRE Study, that includes data from the patients enrolled in the pilot study.

The INSPIRE Study

Our Neuro-Spinal Scaffold implant has been studied in The INSPIRE Study: the "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 an Investigational Device Exemption, or IDE, application for the treatment of neurologically complete thoracic traumatic acute SCI. We commenced an FDA-approved pilot study in 2014 that the FDA approved converting into The INSPIRE Study in January 2016. As of December 31, 2017, we had implanted our Neuro-Spinal Scaffold implant in a total of 19 patients in The INSPIRE Study, 16 of whom reached the six-month primary endpoint visit, and three of whom died. In July 2017, after the third patient death, enrollment of patients in The INSPIRE Study was placed on hold as we engaged with the FDA to address the patient deaths. We subsequently closed enrollment in The INSPIRE Study and will follow the remaining active subjects until completion. Following discussions with the FDA, in March 2018, we received FDA approval for a randomized controlled trial to supplement the existing clinical evidence for the Neuro-Spinal Scaffold implant that we obtained from The INSPIRE Study. We refer to this herein as the INSPIRE 2.0 Study.

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The purpose of The INSPIRE Study, which was the original study, was to evaluate whether the Neuro-Spinal Scaffold implant is safe and demonstrates probable benefit for the treatment of complete T2-T12 neurological level of injury, or (NLI), SCI. The primary endpoint was defined as the proportion of patients achieving an improvement of at least one AIS grade at six months' post-implantation. Additional endpoints included measurements of pain, sensory and motor scores, bladder and bowel function, Spinal Cord Independence Measure (a disability scale for patients with SCI), and quality of life. The INSPIRE Study included an Objective Performance Criterion, or 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, or HDE, approval. At the time enrollment of patients in The INSPIRE Study was placed on hold, the OPC was 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 approved the enrollment of up to 30 patients in The INSPIRE Study so that there would be at least 20 evaluable patients at the primary endpoint analysis, accounting for events such as screen failures or deaths that would prevent a patient from reaching the primary endpoint visit. Of the 19 patients implanted in The INSPIRE Study, 16 patients have reached the six-month primary endpoint visit. Of these 16, seven had improved from complete AIS A SCI to incomplete SCI (two patients to AIS C and five patients to AIS B) at the six-month primary endpoint visit and nine had not demonstrated improvement at that visit. Three of the seven patients who improved were assessed to have AIS B SCI at the six-month primary endpoint and were later assessed to have improved to AIS C SCI at the 12 or 24-month visits. Two of the 16 patients were initially 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 six-month examination. One of these two was then assessed at the six-month visit to have improved again to AIS B and the other remained AIS A. Since we have closed enrollment, the target of enrolling 20 evaluable patients into The INSPIRE Study will not be reached.

The FDA had previously recommended that we include a randomized, concurrent control arm in The INSPIRE Study. Acting on the FDA's recommendation, we proposed and received approval for the INSPIRE 2.0 Study (described below) to supplement the existing clinical evidence for the Neuro-Spinal Scaffold implant. In addition, as one source of comparator data, we initiated the Contemporary Thoracic SCI Registry Study, or the CONTEMPO Registry Study. The CONTEMPO Registry Study utilizes 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, or NACTN, as well as the Model Systems Registry and the European Multicenter Study about Spinal Cord Injury, or EMSCI. We have submitted a protocol for the CONTEMPO Registry Study to the FDA and we announced top-line findings from CONTEMPO in March 2018 from a total of 170 patients from the three registries: 12 individuals from NACTN, 64 from EMSCI, and 94 from the Model Systems Registry. AIS conversion rates at approximately six months post-injury varied from 16.7% – 23.4% across the three registries. In two of the registries, there was a skew of the patient population to low (T10-T12) thoracic injuries, representing 46-47% of the registry population. This compares to just four out of sixteen patients (25%) in follow-up in the INSPIRE study with low thoracic injuries. Patients with low thoracic injuries are known to have the best prognoses, and the conversion rates

were the highest in the low thoracic group in all three registries and the INSPIRE study. When all three registries were normalized to the INSPIRE patient population distribution across T2-T5, T6-T9 and T10-T12 injury groups, the normalized conversion rate for CONTEMPO registries ranged from 15.5%-20.6%. We cannot be certain what additional information or studies will be required by the FDA to approve our HDE submission.

INSPIRE 2.0 Study

Our Neuro-Spinal Scaffold implant has been approved to be studied under our approved IDE in the INPSIRE 2.0 Study, which is titled the "Randomized, Controlled, Single-blind Study of Probable Benefit of the Neuro-Spinal Scaffold™ for Safety and Neurologic Recovery in Subjects with Complete Thoracic AIS A Spinal Cord Injury as Compared to Standard of Care." The purpose of the INSPIRE 2.0 Study is to assess the overall safety and probable benefit of the Neuro-Spinal Scaffold for the treatment of neurologically complete thoracic traumatic acute SCI. The INSPIRE 2.0 Study is designed enroll 10 subjects into each of the two study arms, which we refer to as the Scaffold Arm and the Comparator Arm. Patients in the Comparator Arm will receive the standard of care, which is spinal stabilization without dural opening or myelotomy. The INSPIRE 2.0 Study is a single blind study, meaning that the patients and

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assessors are blinded to treatment assignments. The FDA approved the enrollment of up to 35 patients in this study so that there would be at least 20 evaluable patients (10 in each study arm) at the primary endpoint analysis, accounting for events such as screen failures or deaths that would prevent a patient from reaching the primary endpoint visit. We expect to conduct the INSPIRE 2.0 Study at up to 25 sites in the United States. Enrolling patients in the INSPIRE 2.0 Study will also require the approvals of the institutional review boards, or IRBs, at each clinical site. We estimate that from study initiation, enrollment will take approximately 18 months, and the total time to completion of the INSPIRE 2.0 Study is estimated to be two years from study initiation. We are in the process of initiating the INSPIRE 2.0 Study, and subject to successful IRB approvals, we anticipate that the first patient in the INSPIRE 2.0 Study will be enrolled in the fourth quarter of 2018.

The primary endpoint is defined as the proportion of patients achieving an improvement of at least one AIS grade at six months post-implantation. Assessments of AIS grade are at hospital discharge, three months, six months, 12 months and 24 months. The definition of study success for INSPIRE 2.0 is that the difference in the proportion of subjects who demonstrate an improvement of at least one grade on AIS assessment at the six-month primary endpoint follow-up visit between the Scaffold Arm and the Comparator Arm must be equal to or greater than 20%. In one example, if 50% of subjects in the Scaffold Arm have an improvement of AIS grade at the six-month primary endpoint and 30% of subjects in the Comparator Arm have an improvement, then the difference in the proportion of subjects who demonstrated an improvement is equal to 20% (50% minus 30% equals 20%) and the definition of study success would be met. In another example, if 40% of subjects in the Scaffold Arm have an improvement of AIS grade at the six-month primary endpoint and 30% of subjects in the Comparator Arm have an improvement, then the difference in the proportion of subjects who demonstrated an improvement is equal to 10% (40% minus 30% equals 10%) and the definition of study success would not be met. Additional endpoints include measurements of changes in NLI, sensory levels and motor scores, bladder, bowel and sexual function, pain, Spinal Cord Independence Measure, and quality of life.

Although The INSPIRE Study is 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. Similarly, while our INSPIRE 2.0 Study is structured with a definition of study success requiring a minimum difference between study arms in the proportion of subjects achieving improvement, that success definition is not the only factor that the FDA would evaluate in the future HDE application. Approval is not guaranteed if the OPC is met for The INSPIRE Study or the definition of study success is met for the INSPIRE 2.0 Study, and even if the OPC or definition of study success are 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.

In 2016, the FDA accepted our proposed HDE modular shell submission and review process for the Neuro-Spinal Scaffold implant. 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 each module, 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 all three modules, which constitutes

the complete HDE submission, the FDA makes a filing decision that may trigger the review clock for an approval decision. We submitted the first module in March 2017 and received feedback in June 2017. We plan to submit an updated clinical module in the fourth quarter of 2019. The HDE submission will not be complete until the manufacturing and clinical modules are also submitted.

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

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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 2017 Annual Report.

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

Results of Operations

Comparison of the Three Months Ended September 30, 2018 and 2017

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 September 30, 2018 were $0.9 million, a decrease of $2.0 million compared to the three months ended September 30, 2017. The decrease in research and development expenses for the three months ended September 30, 2018, is attributable to a decrease in compensation related expenses and stock compensation expense of $1.1 million and $0.1 million respectively, driven by the restructuring activities from 2017, a decrease in clinical trial costs and consulting cost of $0.2 million and $0.1 million respectively, due to The INSPIRE Study being placed on hold, a decrease in legal costs of $0.2 million, a decrease in administrative and operating costs of $0.1 million as a result of cost cutting measures initiated by the Company in 2018, a decrease in depreciation expense of $0.1 million, a decrease in recruiting costs $0.1 million and a decrease in facilities and rent expense of $0.1 million as a result of the as a result of the assignment of the commercial lease for our office, laboratory and manufacturing space in Cambridge, Massachusetts, which we refer to as the Cambridge Lease.

General and Administrative Expenses

General and administrative expenses consisted primarily of payroll, rent, and professional services. General and administrative expenses for the three months ended September 30, 2018 were $1.2 million, a decrease of $2.2 million compared to the three months ended September 30, 2017. The decrease in general and administrative expenses for the

three months ended September 30, 2018 is attributable to a decrease in stock compensation and compensation related expense of $0.9 million and $0.7 million respectively, driven by the restructuring activities from 2017, a decrease in legal fees of $0.5 million and a decrease in facilities and rent expenses of $0.2 million as a result of the assignment of the Cambridge Lease. These decreases were offset by an increase in consulting expenses of $0.2 million.

Other Income and Expense

Other expenses for the three months ended September 30, 2018 was a loss of $1.1 million, which was comprised of derivative loss of $2.0 million, other income of $0.8 million primarily made up of a settlement agreement with a former vendor, interest income of $81 thousand and interest expense of $10 thousand. Other expenses for the three months ending September 30, 2017 was a loss of $3.0 million, which was comprised of interest income of $43 thousand, interest expense of $18 thousand, and a derivative loss of $3.1 million due primarily to the impact of the August 2017 warrant exchange.

Comparison of the Nine Months Ended September 30, 2018 and 2017

Research and Development Expenses

Research and development expenses for the nine months ended September 30, 2018 were $3.4 million, a decrease of $6.2 million compared to the nine months ended 2017. The decrease in research and development expenses for the nine months ended September 30, 2018 is attributable to a decrease in compensation related expenses and stock compensation expenses of $2.2 million and $0.8 million respectively, driven by the restructuring activities from 2017, a decrease in clinical trial and consulting costs of $0.9 million and $0.7 million respectively, due to The INSPIRE Study

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being placed on hold, a decrease in facilities and rent expense of $0.4 million as a result of the Cambridge lease assignment, a decrease in administrative and operating costs of $0.3 million as a result of cost cutting measures initiated by the Company in 2018, a decrease in depreciation expense of $0.2 million, a decrease in recruiting costs of $0.2 million, a decrease in legal fees of $0.2 million and a decrease in travel related expenses of $0.2 million.

General and Administrative Expenses

General and administrative expenses for the nine months ended September 30, 2018 were $6.4 million, a decrease of $4.0 million compared to the nine months ended September 30, 2017. The decrease in general and administrative expenses for the nine months ended September 30, 2018 is attributable to a decrease in stock compensation and compensation related expenses of $2.3 million and $0.7 million respectively, driven by the restructuring activities from 2017, a decrease in facilities and rent expenses of $0.5 million as a result of the Cambridge lease assignment, a decrease in legal fees of $0.3 million, a decrease in travel related expenses of $0.2 million and a decrease in depreciation expense of $0.1 million. These decreases were offset by an increase in consulting expenses of $0.2 million

Other Income and Expense

Other expenses for the nine months ended September 30, 2018 was in a loss of $11.1 million, which was comprised of derivative loss of $12.2 million, other income of $0.9 million primarily made up of a settlement agreement with a former vendor, interest income of $159 thousand and interest expense of $36 thousand. Other expenses for the nine months ended September 30, 2017 was a loss of $2.2 million, which was comprised of interest income of $152 thousand, interest expense of $58 thousand, and a derivative loss of $2.3 million due to the impact of the August 2017 warrant exchange and the change in the fair value of the warrant liability since December 31, 2016.

Liquidity and Capital Resources

Since inception, we have devoted substantially all of our efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets, and raising capital. At September 30, 2018, our accumulated deficit was $204.8 million. Since our inception, we have historically financed our operations primarily through the sale of equity related securities.

At September 30, 2018, we had total assets of $21.5 million, total liabilities of $3.0 million, and total stockholders' equity of $18 million. For the nine months ended September 30, 2018, we recorded a net loss of $20.9 million. We have not achieved profitability and may not be able to realize sufficient revenue to achieve or sustain profitability in the future. We do not expect to be profitable in the next several years, but rather expect to incur additional operating losses. The financing we closed in June 2018, described in more detail below, provided necessary funding to fund operations for at least the next twelve months. 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, pursuit of regulatory approvals, acquisition of capital equipment, laboratory and office facilities, 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 other collaborations, strategic alliances and licensing arrangements.

Financings Transactions

In June 2018, we closed an underwritten public offering of an aggregate of 1,378,400 Common Units, at an offering price of $2.00 each, each comprised of one share of our common stock, par value $0.00001 per share and one Series A warrant to purchase one share of common stock. The public offering also included 6,242,811 pre-funded units at an offering price of $1.99 each, each comprised of one pre-funded Series B Warrant and one Series A warrant to purchase one share of common stock. Each Series A warrant has an exercise price of $2.00 per share, exercisable immediately from the date of issuance and expires five years from the date of issuance. Each Series B warrant has an exercise price of $0.01 per share, exercisable immediately from the date of issuance and expires twenty years from the date of issuance. The net proceeds to us, after deducting the underwriting discounts and commissions and other offering

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expenses, were $13.5 million. During the nine months ended September 30, 2018, we issued an aggregate of 5,478,002 shares of common stock upon the exercise of Series B warrants for aggregate proceeds of $55 thousand.

In September 2018, we entered into the Ladenburg Warrant Amendment with Continental that amends the Warrant Agency Agreement and the 2018 Warrants. See Notes 9,11 and 12 to our Consolidated Financial Statements in Item1 of this report for more information about the Ladenburg Warrant Amendment.

In January 2018, we entered into a purchase and a registration rights agreement with Lincoln Park Capital Fund, LLC, which we refer to as Lincoln Park, under which we have the right to sell up to $15 million in shares of our common stock to Lincoln Park over a twenty-four-month period, subject to certain limitations and conditions set forth in the purchase agreement and registration rights agreement. On May 30, 2018 at our Annual Meeting of Stockholders, our stockholders approved an increase to the number of shares of common stock available for issuance and sale by us to Lincoln Park, including our prior issuances and sales of shares of common stock to Lincoln Park since January 2018, up to 1,200,000 shares of common stock. In accordance with the terms of the purchase agreement, at the time we signed the purchase agreement and the registration rights agreement, we issued 17,192 shares to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the purchase agreement and recorded $627 thousand in deferred offering costs. During the nine months ended September 30, 2018 we sold an aggregate of 256,804 shares to Lincoln Park, for aggregate proceeds of $3.1 million net of issuance costs.

On August 10, 2017, we entered into exchange agreements with certain holders of warrants dated May 9, 2014, which we refer to as the 2014 Warrants. Pursuant to the exchange agreements, certain of the 2014 Warrants were exchanged for shares of common stock equivalent to 3.5 times the number of shares of common stock issuable to such holders upon exercise, at the $96.75 exercise price under the warrants as of the date of the exchanges. We issued an aggregate of 80,857 shares of common stock to the participating warrant holders in exchange for their 2014 Warrants for the purchase of an aggregate of 23,102 shares of common stock. We subsequently cancelled and terminated those 2014 Warrants exchanged in this transaction. Following the warrant exchange, there were additional 2014 Warrants to purchase shares of common stock that remained outstanding, which we refer to as the Outstanding 2014 Warrants. As a result of our issuance of common stock in exchange for certain of the 2014 Warrants, the exercise price of the Outstanding 2014 Warrants was adjusted downwards from $96.75 per share to $20.75 per share and additional warrants were issued such that the Outstanding 2014 Warrants were exercisable for an aggregate of 1,941 shares of common stock. The Outstanding 2014 Warrants were subject to further adjustment in the event of sales of our common stock at a price per share less than the exercise price of the Outstanding 2014 Warrants then in effect (or securities convertible or exercisable into common stock at a conversion or exercise price less than the exercise price then in effect). In the fourth quarter of 2017, we entered into warrant cancellation agreements with certain remaining holders of the Outstanding 2014 Warrants to cancel and terminate such warrants for total cash consideration of $40 thousand. During the nine months ended September 30, 2018, we entered into warrant cancellation agreements with certain remaining holders of the Outstanding 2014 Warrants to cancel and terminate such warrants for total cash consideration of $14 thousand. As of September 30, 2018, the remaining Outstanding 2014 Warrants were exercisable for an aggregate of 307 shares of common stock.

Facility Changes

In May 2018, we assigned the Cambridge Lease to a third party, who assumed from us all of our remaining rights and obligations under the lease. Concurrently with the lease assignment, we entered into a sublease for 5,104 square feet of the space, originally part of the Cambridge Lease, from the third party to which we assigned the lease. The sublease ends on October 31, 2023 and contains rent holidays and rent escalation clauses. In order to obtain the consent of our lender for these facility changes and the sale of certain assets, we repaid $300 thousand of principal on our loan and recorded an impairment charge of $48 thousand. For more information, see Note 7 and Note 8 to the notes to our Consolidated Financial Statements in Item 1 of this report.

Cashflows

Net cash used in operating activities for the nine months ended September 30, 2018 was $9.3 million, as compared to net cash used in operating activities of $15.6 million for the nine months ended September 30, 2017. The change in net cash used in operating activities for the nine months ended September 30, 2018 as compared to the same period in the prior year was primarily due to an decrease in our net loss of $1.2 million, an increase in the change in

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derivative loss of $10 million, a decrease in share-based compensation expense of $3.1 million, a decrease in the change in other assets of $866 thousand, a gain on lease assignment of $603 thousand and a decrease in depreciation and amortization expense of $312 thousand.

Net cash used in investing activities for the nine months ended September 30, 2018 was $65 thousand attributable to purchases of capital equipment. This compares to net cash from in investing activities for the nine months ended September 30, 2017 of $10.8 million attributable to sales of marketable securities of $19.1 million offset by purchases of marketable securities of $8.3 million.

Net cash provided by financing activities for the nine months ended September 30, 2018 was $15.9 million consisting primarily of $16.5 million in proceeds from the issuance of common stock associated with the June 2018 underwritten public offering and the Lincoln Park financing agreement, offset by $636 thousand in loan repayments. This compares to net cash of $238 thousand used in financing activities for the nine months ended September 30, 2017 which consists of proceeds from the exercise of a stock option and Employee Stock Purchase Plan issuances of $77 thousand, offset in part by loan repayments of $315 thousand.

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

As of September 30, 2018, 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 2017 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 2017 Annual Report. As of September 30, 2018, there were no material changes in our exposure to market risk compared to December 31, 2017.

Item 4.Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2018. 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 September 30, 2018, the Company’s chief

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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.

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 September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

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 $20.9 million for the nine months ended September 30, 2018. As of September 30, 2018, we had an accumulated deficit of $204.8 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 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. 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 clinical development of our Neuro-Spinal Scaffold implant;

· initiate or restart the research and development of other product candidates;

· have our product candidates manufactured for clinical trials and for commercial sale;

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- 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 current and future 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.

We will need additional funding in the future. 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 will increase in connection with our ongoing activities, particularly as we conduct our INSPIRE 2.0 Study, and as we seek regulatory approval for our Neuro-Spinal Scaffold implant. In addition, if we obtain regulatory approval for any of our current or future 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 trials for our Neuro-Spinal Scaffold implant and any other product candidates that we may develop or acquire, including our INSPIRE 2.0 Study;

- 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, 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;

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- 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;

- 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.

Our independent registered public accounting firm expressed substantial doubt as to our ability to continue as a going concern in its report dated March 12, 2018 included in our Form 10-K as filed with the Securities and Exchange Commission, or the SEC, on March 12, 2018. Although we completed a public offering of shares of our common stock and warrants to purchase shares of our common stock in June 2018 which resulted in net proceeds to us, after deducting the underwriting discounts and commissions and other offering expenses, of $13.5 million, 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.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Code. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses, or NOLs to 80% of current year taxable income and elimination of NOL carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such NOLs may be carried forward indefinitely), one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many

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business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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

We have generated significant net operating loss carryforwards, or NOLs, and research and development tax credits, or 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. Federal NOLs generated on or before December 31, 2017 can generally be carried back two years and carried forward for up to twenty years and can be applied to offset 100% of taxable income in such years. Under newly enacted federal income tax law, however, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, but may not be carried back and the deductibility of such federal NOLs is limited to 80% of taxable income in such years. It is uncertain how various states will respond to the newly enacted federal tax law.

In addition, our ability to utilize the NOLs and R&D credits is subject to the rules of Sections 382 and 383, respectively, of the Internal Revenue Code of 1986, as amended, which we refer to as the Code. 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.

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

We continue to actively evaluate business partnerships and acquisitions of businesses, technologies, or intellectual property rights that we believe would be necessary, useful, or complementary to our current business. Any such acquisition may require assimilation of the operations, products or product candidates, and personnel of the acquired business and the training and integration of its employees, and could substantially increase our operating costs, without any offsetting increase in revenue. 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 are wholly dependent on the success of one product candidate, the Neuro-Spinal Scaffold implant. Even if we are able to complete clinical development and 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 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 pre-market approval, or PMA, for our product candidate, 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 regulatory approval process required by the U.S. Food and Drug Administration, or the FDA, 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.

The clinical trials of any of our current or future product candidates are, and the manufacturing and marketing of any such 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 such product candidates.

We have experienced delays and may experience further delays in our clinical development of our Neuro-Spinal Scaffold implant. Clinical trials for future product candidates may also experience delays or may not be able to commence.

Before we can obtain regulatory approval for the sale of our Neuro-Spinal Scaffold implant, we must complete the clinical studies that are required. In July 2017, The INSPIRE Study of our Neuro-Spinal Scaffold implant was placed

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on hold following the third patient death in the trial. We subsequently closed enrollment in The INSPIRE Study and will follow the active patients until completion. We have proposed, and the FDA has approved the INSPIRE 2.0 Study. We may not be able to pursue the currently defined clinical path forward successfully, or in a timely manner or that is aligned with our cash resources. The INSPIRE 2.0 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 scaffold implants to supply to our clinical sites, failure to demonstrate safety and probable benefit of our Neuro-Spinal Scaffold implant, lack of adequate funding to continue the clinical trial, or unforeseen safety issues. Enrolling patients the INSPIRE 2.0 Study and any other clinical trial of our Neuro-Spinal Scaffold implant will also require the approval of the institutional review boards, or IRBs at each clinical site.

In addition, 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 of the 16 evaluable patients were initially 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. Of these two patients, one patient had converted back to AIS B and the other remained at AIS A at the six-month examination. 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 implemented procedures in The INSPIRE Study and the INSPIRE 2.0 Study, and will also implement procedures in any future clinical study 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.

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, or 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 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. In addition, regulatory agencies may require an audit with respect to the conduct of a clinical trial, which could cause further delays or increase costs. For example, in December 2017, we and several of our clinical sites and our CRO were subject to an FDA inspection in association with The INSPIRE Study. At the close of the inspection at InVivo, the FDA issued a Form 483 with two observations relating to our oversight of clinical trial sites in The INSPIRE Study. We sought, and will continue to seek, input from the FDA regarding the scope and timing of our proposed remediation efforts and the FDA has indicated that our corrective actions appear adequate. We cannot be certain that we will not be subject to additional regulatory action by the FDA. We anticipate that our remediation efforts will add costs to our clinical development plans. 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

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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, in July 2017 we halted enrollment in the study, and subsequently closed enrollment in the study. We may experience similar delays with our INSPIRE 2.0 Study. 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.

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 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 the HDE regulatory pathway 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

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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 ready 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 implant. 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 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. While we expect The INSPIRE Study to serve as one source of data used to support HDE approval in the future, we will not complete full enrollment of that study. In addition, although The INSPIRE Study is 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.

The FDA had previously recommended that we include a randomized, concurrent control arm in the study and we have proposed and received approval for the INSPIRE 2.0 Study. The primary endpoint is defined as the proportion of patients achieving an improvement of at least one AIS grade at six months post-implantation. The definition of study success is that the difference in the proportion of subjects who demonstrate an improvement of at least one grade on AIS assessment at the six-month primary endpoint follow-up visit between the Scaffold Arm and the

Comparator Arm must be equal to or greater than 20%. While our INSPIRE 2.0 Study is structured with a definition of study success requiring a minimum difference between groups in the percentage of subjects achieving improvement, that success definition is not the only factor that the FDA would evaluate in the future HDE application.

Approval is not guaranteed if the OPC is met for The INSPIRE Study or the definition of study success is met for the INSPIRE 2.0 Study, and even if the OPC or definition of study success are 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.

In addition, as one source of comparator data, we initiated 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 either our INSPIRE 2.0 Study or the CONTEMPO Registry Study will be successfully completed. Even if we successfully complete the INSPIRE 2.0 Study and the CONTEMPO Registry Study, we cannot be certain that the FDA will agree that these additional studies provide 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 a higher threshold for evidencing probable benefit. For example, AIS conversion rates at approximately six months post-injury across the three registries used in

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CONTEMPO varied from 16.7% – 23.4%, which are higher than the approximately 15.5% conversion rate from the historical registries that were the basis for the selection of the current OPC for The INSPIRE Study. In the event our clinical data 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 HUD to include additional patient populations beyond our current HUD for complete 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 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 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. With enactment of the FDA Reauthorization Act of 2017, Congress provided that the exemption for HUD / HDE profitability is available as long as the request for an exemption is submitted before October 1, 2022.

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. 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 lengthier and more 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.

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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 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. 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.

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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 System Regulations, or 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 and Good Tissue Practices with respect to any human cells and biologic products we may develop, and International Standards Organization 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 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;

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- testing, labeling, content, and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales, and distribution;
- 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 impede our ability to carry on or expand our operations and could result in 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 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.

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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.

Further, even after we have obtained the proper regulatory clearance or approval to market a product, the FDA may 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 products, or the malfunction of our 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

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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 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 decision to require a recall must be based on an FDA finding that there is 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 manufacture 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.

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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, in the United States, legislative changes have been enacted in the past and further changes are proposed that would impact the Patient Protection and Affordable Care Act, or 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 have been, and may be additional, legislative changes affecting the Affordable Care Act, including repeal of certain provisions of the Affordable Care Act. It remains to be seen, however, precisely what impact legislation to date and any future legislation 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. 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.

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 Scaffold 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 implant 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, or BCH, and the Massachusetts Institute of Technology, or 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

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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 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.

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

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.

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. We have implemented restructurings that have significantly reduced our workforce over the last few months, leaving only key positions filled. On February 2, 2018, we appointed Richard Toselli M.D. as President, Chief Executive Officer, and a director. The loss of any members of senior management or key scientific personnel 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

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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.

Risks Related to Litigation and Legal Compliance

We may face, and in the past have faced, lawsuits, which could divert management's attention and harm our business.

We may face lawsuits, including class action or securities derivative lawsuits. For example, we were previously the subject of a securities derivative lawsuit and securities class action lawsuit, both of which were dismissed in January 2017. 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.

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

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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;

- 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.

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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 has been and may continue to be 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;
- 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.

In the foreseeable future, we do not intend to pay cash dividends on shares of our common stock so any investor gains will be limited to the value of our shares.

We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any gains to stockholders will therefore be limited to the increase, if any, in our share price.

In the event that we fail to satisfy any of the listing requirements of the Nasdaq Capital Market, our common stock may be delisted, which could affect our market price and liquidity.

Our common stock is listed on the Nasdaq Capital Market. For continued listing on the Nasdaq Capital Market, we will be required to comply with the continued listing requirements, including the minimum market capitalization

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standard, the corporate governance requirements and the minimum closing bid price requirement, among other requirements. For example, we were previously listed on the Nasdaq Global Market and on January 23, 2018 we received a deficiency letter from the Listings Qualifications Department of the Nasdaq Stock Market notifying us that, for the prior 30 consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued inclusion on the Nasdaq Global Market. Although we regained compliance with the Bid Price Rule as a result of the reverse stock split we effected on April 16, 2018, we received a notification from the Listing Qualifications Department of the Nasdaq Stock Market on May 11, 2018, notifying us that, based on our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, our stockholders' equity was $8,323,000, and therefore, the we were not in compliance with the minimum stockholders' equity standard which required a minimum of $10,000,000 in stockholders' equity. We elected to transfer to the Nasdaq Capital Market, and the transfer was effective June 19, 2018.

On August 15, 2018, we received a written notification from the Listing Qualifications Department of the Nasdaq Stock Market notifying us that, based on the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, the Company's stockholders' equity was $(1,909,000), and therefore, the Company was not in compliance with Nasdaq Listing Rule 5550(b)(1), which requires a $2,500,000 minimum stockholders' equity standard. Total stockholders' deficit at June 30, 2018 was primarily driven by derivative accounting on the warrants issued as part of our June 2018 public offering. In accordance with such notice, we were requested to provide to Nasdaq, on or before October 1, 2018, our specific plan to regain compliance with all Nasdaq Capital Market listing requirements and our time frame to complete our plan. On October 1, 2018, we submitted a plan to regain compliance with the continued listing requirements of the Nasdaq Capital Market, and Nasdaq has granted us an extension until November 14, 2018 to evidence compliance with all Nasdaq Capital Market listing requirements. If Nasdaq determines that such plan is not sufficient, it will provide written notification that our securities will be delisted. At that time, we may appeal Nasdaq's determination to a hearings panel (the "Panel"). We expect that our stock would remain listed pending the Panel's decision. There can be no assurance that, if we do appeal Nasdaq's determination to the Panel, that such appeal would be successful.

In the event that we fail to satisfy any of the listing requirements of the Nasdaq Capital Market our common stock may be delisted. If our securities are delisted from trading on the Nasdaq Capital Market, and we are not able to list our securities on another exchange our securities could be quoted on the OTC Bulletin Board or on the "pink sheets." As a result, we could face significant adverse consequences including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock," which would require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities (including pursuant to short-form registration statements on Form S-3 or obtain additional financing in the future).

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 publicly traded corporations, or Nevada corporations that elect to be subject to the law, and "interested stockholders" for two years after the interested stockholder first becomes an interested stockholder, unless the corporation's board of directors approves the transaction by which the stockholder becomes an interested stockholder in advance, or the proposed combination in advance of the stockholder becoming an interested stockholder.

The proposed combination may be approved after the stockholder becomes an interested stockholder with preapproval by the board of directors and a vote at a special or annual meeting of stockholders holding at least 60% of the voting power not owned by the interested stockholder or his/her/ its affiliates or associates. After the two-year

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moratorium period, additional stockholder approvals or fair value requirements must be met by the interested shareholder up to four years after the stockholder became an interested stockholder. 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.

Item 6. Exhibits

Exhibit Number	Description
3.1	Articles of Incorporation of InVivo Therapeutics Holdings Corp. as amended (incorporated by reference from Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 as filed with the SEC on August 4, 2016.)
3.2	Certificate of Amendment to Articles of Incorporation of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on June 1, 2017.)
3.3	Certificate of Amendment to Articles of Incorporation of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC June 1, 2018.)
3.4	Certificate of Change Pursuant to NRS 78.209 filed with Nevada Secretary of State, dated April 13 2018 (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on April 16, 2018.)
4.1	Amendment to Warrant Agency Agreement, by and between InVivo Therapeutics Holdings Corp. and Continental Stock Transfer & Trust Company, as Warrant Agent, dated September 27,

	2018 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on September 28, 2018).
4.2	Form of Series A Common Stock Purchase Warrant, as amended (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on September 28, 2018).
4.3	Form of Series B Common Stock Purchase Warrant, as amended (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the SEC on September 28, 2018).
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.

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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

* Management contract or compensatory plan or arrangement.

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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: November 8, 2018	By:	/s/ Richard Toselli
	Name:	Richard Toselli
	Title:	Chief Executive Officer, Principal Executive Officer
Date: November 8, 2018	By:	/s/ Jeffrey Modestino
	Name:	Jeffrey Modestino
	Title:	Principal Financial Officer, Principal Accounting Officer, Treasurer