INVIVO THERAPEUTICS HOLDINGS CORP.
Form S-1
January 29, 2018
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As filed with the Securities and Exchange Commission on January 26, 2018

Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON D.C. 20549

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

INVIVO THERAPEUTICS HOLDINGS CORP.

(Name of registrant in its charter)

Nevada	**3841**	**36-4528166**
(State or other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

One Kendall Square, Suite B14402
Cambridge, MA 02139
(617) 863-5500

(Address and telephone number of principal executive offices and principal place of business)

Richard Toselli, M.D.

Acting Chief Executive Officer

InVivo Therapeutics Holdings Corp.

One Kendall Square, Suite B14402
Cambridge, MA 02139
(617) 863-5500

(Name, address and telephone number of agent for service)

Copies to:

Rosemary G. Reilly, Esq.

Wilmer Cutler Pickering Hale and Dorr LLP

60 State Street

Boston, Massachusetts 02109

(617) 526-6000

APPROXIMATE DATE OF PROPOSED SALE TO THE PUBLIC:

From time to time after this Registration Statement becomes effective.

If any securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box: x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

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

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 7(a)(2)(B) of the Securities Act. o

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered (1)(2)	Proposed Maximum Offering Price Per Security (3)	Proposed Maximum Aggregate Offering Price (3)	Amount of Registration Fee
Common stock, $.00001 par value	10,700,000	$ 0.67	$ 7,169,000	$ 893

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended, or the Securities Act, the shares of common stock offered hereby also include an indeterminate number of additional shares of common stock as may from time to time become issuable by reason of anti-dilution provisions, stock splits, stock dividends, recapitalizations or other similar transactions.

(2) Represents 429,800 shares of common stock previously issued to the selling stockholder named herein, and 10,270,200 shares of common stock that are issuable pursuant to a purchase agreement with the selling stockholder named herein.

(3) Calculated pursuant to Rule 457(c), solely for the purpose of computing the amount of the registration fee, on the basis of the average of the high and low prices of the registrant s common stock quoted on The Nasdaq Global Market on January 24, 2018.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. The selling stockholder may not sell these securities under this prospectus until the registration statement of which it is a part and filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED JANUARY 26, 2018

PRELIMINARY PROSPECTUS

Up to 10,700,000 Shares of Common Stock

This prospectus covers the offer and sale of up to 10,700,000 shares of common stock, $0.00001 par value per share, of InVivo Therapeutics Holdings Corp., a Nevada corporation, by Lincoln Park Capital Fund, LLC, or Lincoln Park. Lincoln Park is also referred to in this prospectus as the Selling Stockholder.

The shares of common stock being offered by the Selling Stockholder have been or may be issued pursuant to the purchase agreement dated January 25, 2018, or the Purchase Agreement, that we entered into with Lincoln Park. See Lincoln Park Transaction for a description of the Purchase Agreement and Selling Stockholder for additional information regarding Lincoln Park. The prices at which Lincoln Park may sell the shares of common stock will be determined by the prevailing market price for the shares of common stock or in negotiated transactions.

We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of the shares of common stock by the Selling Stockholder.

The Selling Stockholder may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. See Plan of Distribution for more information about how the Selling Stockholder may sell the shares of common stock being registered pursuant to this prospectus. The Selling Stockholder is an underwriter within the meaning of Section 2(a)(11) of the Securities Act.

We will pay the expenses incurred in registering the shares of common stock, including legal and accounting fees. See Plan of Distribution.

Our common stock is currently quoted on The Nasdaq Global Market under the symbol NVIV. On January 25, 2018, the last reported sale price of our common stock on The Nasdaq Global Market was $0.665 per share.

Investing in our common stock involves a high degree of risk. Before making any investment in our common stock, you should read and carefully consider the risks described in this prospectus under Risk Factors beginning on page 8 of this prospectus.

You should rely only on the information contained in this prospectus or any prospectus supplement or amendment thereto. We have not authorized anyone to provide you with different information.

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

This prospectus is dated , 2018

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SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements may include, but are not limited to, statements about:

- our limited operating history and history of net losses;

- our ability to raise substantial additional capital to finance our planned operations and to continue as a going concern;

- our ability to define a viable clinical path forward following our ongoing discussions with the U.S. Food and Drug Administration, including our ability to commence a randomized clinical trial to support our existing Humanitarian Device Exemption application;

- our ability to execute our strategy and business plan;

- our ability to obtain regulatory approvals for our current and future product candidates, including our *Neuro-Spinal Scaffold* implant;

- our ability to successfully commercialize our current and future product candidates, including our *Neuro-Spinal Scaffold* implant*;*

- the progress and timing of our current and future development programs;

- our ability to successfully re-open, enroll and complete clinical trials and obtain and maintain regulatory approval of our current and future product candidates;

- our ability to protect and maintain our intellectual property and licensing arrangements;

- our reliance on third parties to conduct testing and clinical trials;

- market acceptance and adoption of our current and future technology and products;

- our ability to promote, manufacture and sell our current and future products, either directly or through collaborative and other arrangements with third parties; and

- our ability to attract and retain key personnel.

In some cases, you can identify forward-looking statements by terms such as may, might, will, should, intends, expects, plans, goals, projects, anticipates, believes, estimates, predicts, potential or continue and similar expressions intended to identify forward-looking st These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail under the heading Risk Factors on page 8 of this prospectus and in our Securities and Exchange Commission filings. Also, these forward-looking statements represent our estimates and assumptions only as of the date of the document containing the applicable statement.

You should read this prospectus completely and with the understanding that our actual future results may be materially different from what we currently expect. We qualify all of the forward-looking statements in the foregoing documents by these cautionary statements.

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ABOUT THIS PROSPECTUS

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. The Selling Stockholder is offering to sell and seeking offers to buy shares of our common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our common stock. The prospectus will be updated and updated prospectuses made available for delivery to the extent required by the federal securities laws.

No person is authorized in connection with this prospectus to give any information or to make any representations about us, the Selling Stockholder, the securities or any matter discussed in this prospectus, other than the information and representations contained in this prospectus. If any other information or representation is given or made, such information or representation may not be relied upon as having been authorized by us or the Selling Stockholder. This prospectus does not constitute an offer to sell, or a solicitation of an offer to buy the securities in any circumstances under which the offer or solicitation is unlawful. Neither the delivery of this prospectus nor any distribution of securities in accordance with this prospectus shall, under any circumstances, imply that there has been no change in our affairs since the date of this prospectus. The prospectus will be updated and updated prospectuses made available for delivery to the extent required by the federal securities laws.

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PROSPECTUS SUMMARY

This summary highlights certain information about us, this offering and selected information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our securities. For a more complete understanding of our company and this offering, we encourage you to read and consider carefully the more detailed information in this prospectus, including the information under the heading Risk Factors in this prospectus on page 8. Except where the context otherwise requires, the terms we, us, our, InVivo or the Company refer to the business of InVivo Therapeutics Holdings Corp., a Nevada corporation, and its wholly-owned subsidiary.

InVivo Therapeutics Holdings Corp.

Business Overview

We are a research and clinical-stage biomaterials and biotechnology company with a focus on treatment of spinal cord injuries, or SCIs. Our mission is to redefine the life of the SCI patient, and we seek to develop treatment options intended to provide meaningful improvement in patient outcomes following SCI. Our approach to treating acute SCIs is based on our investigational *Neuro-Spinal Scaffold* implant, a bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord and is intended to treat acute SCI. 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.

Our Clinical Program

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

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 the FDA, or growth factors. We expect the *Neuro-Spinal Scaffold* implant to be regulated by the FDA as a Class III medical device.

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The INSPIRE Study

Our *Neuro-Spinal Scaffold* implant has been studied in The **INSPIRE** Study: **In**Vivo Study of Probable Benefit of the *Neuro-**Spi**nal Scaffold* for Safety and Neurologic **Re**covery in Subjects with Complete Thoracic AIS A Spinal Cord Injury, under an Investigational Device Exemption application for the treatment of neurologically complete thoracic traumatic acute SCI. We commenced an FDA-approved pilot study in 2015 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 remained in follow-up and had 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 are in ongoing discussions with the FDA and have proposed a randomized controlled trial to supplement the existing clinical evidence for the *Neuro-Spinal Scaffold* implant that we obtained from The INSPIRE Study. We do not anticipate reopening enrollment in The INSPIRE Study. We expect to provide additional clarity on our clinical path forward in the second quarter of 2018.

The purpose of The INSPIRE 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 SCI. The primary endpoint was defined as the proportion of patients achieving an improvement of at least one American Spinal Injury Association Impairment Scale, or 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 are in follow-up and 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. Two of the seven patients who improved and were assessed to have AIS B SCI at the six-month primary endpoint were later assessed to have improved to AIS C SCI at the 12 and 24-month visits, respectively. 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 subjects was then assessed at the six-month visit to have improved again to AIS B and the other remained AIS A. Given that the study has been on hold since July 2017 and that we are discussing an additional study with the FDA, we do not plan to reopen enrollment. As a result, 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 have proposed a randomized controlled trial 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 will utilize existing databases and registries to develop a historical comparator that, to the extent possible, matches patients to those patients enrolled in The INSPIRE Study. The CONTEMPO Registry Study is designed to provide comprehensive natural history benchmarks for The INSPIRE Study results that include SCI patients with similar baseline characteristics treated since 2006. The CONTEMPO Registry Study includes data from the Christopher & Dana Reeve Foundation North American Clinical Trials Network Registry, as well as the Model Systems Registry and the European Multicenter Study about Spinal Cord Injury. We anticipate that there will be between 100 to 200 patients in the CONTEMPO Registry Study. We have submitted a protocol for the CONTEMPO Registry Study to the FDA. We cannot be certain what additional information or studies will be required by the FDA to approve our HDE submission.

As noted above, we are continuing to discuss with the FDA the set of data that will be used to support HDE approval in the future. While we expect The INSPIRE Study to serve as one source of data, we no longer expect to

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complete full enrollment of that study. In addition, although The INSPIRE Study is currently structured with the OPC as the primary component for demonstrating probable benefit, the OPC is not the only variable that the FDA would evaluate when reviewing The INSPIRE Study data as part of a future HDE application. Approval is not guaranteed if the OPC is met, and even if the OPC is not met, the FDA may approve a medical device if probable benefit is supported by a comprehensive review of all clinical endpoints and preclinical results, as demonstrated by the sponsor s body of evidence.

Although we continue discussions with the FDA regarding the appropriate supporting clinical data, we have also begun the process of submitting the marketing application for the product to the FDA. 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 modules, which are individual sections of the HDE submission, on a rolling basis. Following the submission of each module, the FDA reviews and provides feedback, typically within 90 days, allowing the applicant to receive feedback and potentially resolve any deficiencies during the review process. Upon receipt of the final module, which constitutes the complete HDE submission, the FDA makes a filing decision which may trigger the review clock for an approval decision. We submitted the first module in March 2017 and received feedback in June 2017. We are working on responses to the FDA s questions and plan to submit an updated preclinical module in 2018. The HDE submission will not be complete until the manufacturing and clinical modules are also submitted.

Corporate Information

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

Our principal executive offices are located in leased premises at One Kendall Square, Suite B14402, Cambridge, Massachusetts 02139. Our telephone number is (617) 863-5500. We maintain a website at www.invivotherapeutics.com. Information contained on, or accessible through, our website is not a part of, and is not incorporated by reference into, this prospectus supplement or the accompanying prospectus.

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The Offering

Common stock offered by the Selling Stockholder	10,700,000 shares consisting of: • 429,800 shares of our common stock issued to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement, or the Commitment Shares; and • 10,270,200 shares we may sell to Lincoln Park under the Purchase Agreement from time to time after the date of this prospectus.
Common stock outstanding before the offering	34,279,467 shares
Common stock outstanding after the offering	44,979,467 shares.
Use of proceeds	We will receive no proceeds from the sale of shares of common stock by Lincoln Park in this offering. We may receive up to $15,000,000 in aggregate gross proceeds under the Purchase Agreement from any sales we make to Lincoln Park pursuant to the Purchase Agreement after the date of this prospectus. Any proceeds that we receive from sales to Lincoln Park under the Purchase Agreement will be used for working capital and general corporate purposes. See Use of Proceeds.
Symbol on The NASDAQ Global Market	NVIV
Risk factors	You should carefully consider the information set forth in this prospectus and, in particular, the specific factors set forth in the Risk Factors section beginning on page 8 of this prospectus before deciding whether or not to invest in our common stock.

Purchase Agreement with Lincoln Park

On January 25, 2018, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has agreed to purchase from us up to an aggregate of $15,000,000 of our common stock (subject to certain limitations) from time to time over the term of the Purchase Agreement. Also on January 25, 2018, we entered into a registration rights agreement, or the Registration Rights Agreement, with Lincoln Park pursuant to which we have filed with the Securities and Exchange Commission, or the SEC, the registration statement that includes this prospectus to register for resale under the Securities Act the shares of common stock that have been or may be issued to Lincoln Park under the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, at the time we signed the Purchase Agreement and the Registration Rights Agreement, we issued 429,800 Commitment Shares to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement.

We do not have the right to commence any sales of our common stock to Lincoln Park under the Purchase Agreement until certain conditions set forth in the Purchase Agreement, all of which are outside of Lincoln Park s control, have been satisfied, including that the SEC has declared effective the registration statement that includes this prospectus, which we refer to as the Commencement. Thereafter, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase an initial amount of shares of our common stock upon the Commencement, as

well as shares of our common stock in amounts up to 150,000 shares on any single business day from and after the Commencement, which amounts may be increased to up to 250,000 shares of our common stock depending on the market price of our common stock at the time of sale, subject to a maximum of $1,000,000 per purchase. In addition, we have the right, from time to time after Commencement and at our sole discretion, to direct Lincoln Park to purchase other accelerated amounts, additional accelerated amounts and/or additional amounts of our common stock under certain circumstances. We will control the timing and

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amount of any sales of our common stock to Lincoln Park. The purchase price of the shares that may be sold to Lincoln Park under the Purchase Agreement will be based on the market price of our common stock preceding the time of sale as computed under the Purchase Agreement. The purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the business days used to compute such price. We may at any time in our sole discretion terminate the Purchase Agreement without fee, penalty or cost upon one business days notice. There are no restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement or Registration Rights Agreement, other than a prohibition on entering into certain equity line of credit, at-the-market or other similar offerings, as described in the Purchase Agreement. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

As of December 31, 2017, there were 34,274,776 shares of our common stock outstanding, of which 33,938,414 shares were held by non-affiliates, excluding the 429,800 Commitment Shares that we have already issued to Lincoln Park under the Purchase Agreement. Although the Purchase Agreement provides that we may sell up to $15,000,000 of our common stock to Lincoln Park, only 10,700,000 shares of our common stock are being offered under this prospectus, which represents: (i) 429,800 shares that we already issued to Lincoln Park as a commitment fee for making the commitment under the Purchase Agreement, and (ii) an additional 10,270,200 shares which may be issued to Lincoln Park in the future under the Purchase Agreement, if and when we sell shares to Lincoln Park under the Purchase Agreement. Depending on the market prices of our common stock at the time we elect to issue and sell shares to Lincoln Park under the Purchase Agreement, we may need to register for resale under the Securities Act additional shares of our common stock in order to receive aggregate gross proceeds equal to the $15,000,000 total commitment available to us under the Purchase Agreement. If all of the 10,700,000 shares offered by Lincoln Park under this prospectus were issued and outstanding as of the date hereof, such shares would represent 31.2% of the total number of shares of our common stock outstanding and 31.5% of the total number of outstanding shares held by non-affiliates, in each case as of December 31, 2017. If we elect to issue and sell more than the 10,700,000 shares offered under this prospectus to Lincoln Park, which we have the right, but not the obligation, to do, we must first register for resale under the Securities Act any such additional shares, which could cause additional substantial dilution to our stockholders. The number of shares ultimately offered for resale by Lincoln Park is dependent upon the number of shares we sell to Lincoln Park under the Purchase Agreement.

Under applicable rules of The Nasdaq Global Market, in no event may we issue or sell to Lincoln Park under the Purchase Agreement more than 19.99% of the shares of our common stock outstanding immediately prior to the execution of the Purchase Agreement (which is 6,852,465 shares based on 34,279,467 shares outstanding immediately prior to the execution of the Purchase Agreement), or the Exchange Cap, unless (i) we obtain stockholder approval to issue shares of common stock in excess of the Exchange Cap or (ii) the average price of all applicable sales of our common stock to Lincoln Park under the Purchase Agreement equals or exceeds $0.711 per share (which represents the closing consolidated bid price of our common stock on January 24, 2018, plus an incremental amount to account for our issuance of the Commitment Shares to Lincoln Park), such that the transactions contemplated by the Purchase Agreement are exempt from the Exchange Cap limitation under applicable Nasdaq rules. In any event, the Purchase Agreement specifically provides that we may not issue or sell any shares of our common stock under the Purchase Agreement if such issuance or sale would breach any applicable rules or regulations of The Nasdaq Global Market.

The Purchase Agreement also prohibits us from directing Lincoln Park to purchase any shares of common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by Lincoln Park, would result in Lincoln Park and its affiliates having beneficial ownership, at any single point in time, of more than 4.99% of the then total outstanding shares of our common stock, or the Beneficial Ownership Cap, as calculated pursuant to Section 13(d) of the Exchange Act and Rule 13d-3 thereunder.

Issuances of our common stock in this offering will not affect the rights or privileges of our existing stockholders, except that the economic and voting interests of each of our existing stockholders will be diluted as a result of any such issuance. Although the number of shares of common stock that our existing stockholders own will not decrease, the shares owned by our existing stockholders will represent a smaller percentage of our total outstanding shares after any such issuance to Lincoln Park.

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RISK FACTORS

An investment in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should consider carefully the risks described below and those described in our Annual Report on Form 10-K for the year ended December 31, 2016 and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2017. You should carefully consider the risks described therein and the other information in this prospectus before you decide to invest in our common stock. Such risks and uncertainties are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect us. If any of those risks were to occur, our financial condition, operating results and prospects, and the market price of our common stock would likely decline and you could lose all or part of your investment.

Risks Related to this Offering and Our Common Stock

The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

On January 25, 2018, we entered into the Purchase Agreement with Lincoln Park, pursuant to which Lincoln Park has committed to purchase up to $15,000,000 of our common stock. Upon the execution of the Purchase Agreement, we issued 429,800 Commitment Shares to Lincoln Park as a fee for its commitment to purchase shares of our common stock under the Purchase Agreement. The remaining shares of our common stock that may be issued under the Purchase Agreement may be sold by us to Lincoln Park at our discretion from time to time over a 24-month period commencing after the satisfaction of certain conditions set forth in the Purchase Agreement, including that the SEC has declared effective the registration statement that includes this prospectus. The purchase price for the shares that we may sell to Lincoln Park under the Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

We generally have the right to control the timing and amount of any future sales of our shares to Lincoln Park. Additional sales of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some, or none of the additional shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

Investors may experience dilution of their ownership interests because of the future issuance of additional shares of our common stock.

As of December 31, 2017, there were outstanding warrants to purchase 2,166,149 shares of our common stock, outstanding options to purchase 3,369,245 shares of our common stock and outstanding restricted stock units to purchase 500,000 shares of our common stock. We expect to issue additional equity awards to compensate employees, consultants, and directors, and may issue additional shares to raise capital, to acquire other companies or technologies, to pay for services, or for other corporate purposes. Any such issuances will have the effect of diluting the interest of current stockholders. The future issuance of any such additional shares of common stock may create downward pressure on the trading price of the common stock. There can be no assurance that we will not be required to issue additional shares, warrants, or other convertible securities in the future in conjunction with any capital raising efforts, including at a price (or exercise prices) below the price at which shares of our common stock are currently quoted on the Nasdaq Global Market.

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Certain of our outstanding warrants may be adjusted as a result of this offering, which would result in dilution to our stockholders.

Our outstanding warrants issued on or about May 9, 2014, or the 2014 Warrants, to purchase a total of 13,429 shares of common stock as of December 31, 2017 at a current exercise price of $0.83 per share contain so-called full-ratchet anti-dilution provisions. These anti-dilution provisions may be triggered by the issuance of the securities being offered hereby or upon any future issuance by us of shares of our common stock or common stock equivalents at a price per share below the then-exercise price of the warrants, subject to some exceptions. The determination of whether common stock was sold at a price below the exercise price of the 2014 Warrants is made pursuant to a formula set forth in the 2014 Warrants which, among other things, assigns value to warrants accompanying the issuance of common stock. As a result of the issuance of the Commitment Shares, the exercise price of the 2014 Warrants was adjusted downwards from $0.83 to $0.70 per share and the outstanding 2014 Warrants became exercisable for 15,924 shares of common stock. Assuming that, as a result of this offering, the exercise price of the 2014 Warrants will be further adjusted downwards from $0.70 to $0.25 per share, which is the lowest price at which we may deliver a Regular Purchase Notice (as defined in the Purchase Agreement) to Lincoln Park under the Purchase Agreement, the 2014 Warrants would be exercisable for approximately 44,588 shares of common stock, which will result in further dilution to our stockholders. In the event that the exercise price is adjusted to a price below the assumed exercise price of $0.25 per share, the number of shares of common stock for which the 2014 Warrants would be exercisable would further increase.

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

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

Risks Related to Our Financial Position and Need for Additional Capital

There is substantial doubt about our ability to continue as a going concern, which will affect our ability to obtain future financing and may require us to curtail our operations. Our clinical trial has been on hold since July 2017 and we may not be successful at defining a clinical path forward, and, even if we are, we may not be able to raise the funds to complete such clinical path, either of which may cause us to curtail or cease operations.

In July 2017, enrollment of patients in The INSPIRE Study of our *Neuro-Spinal Scaffold* implant was placed on hold following the third patient death in the trial. Since our clinical trial was put on hold in July 2017, we have been in discussions with the Food and Drug Administration, or FDA, to define a clinical path forward. As part of the ongoing discussions with the FDA, we have proposed a randomized controlled trial to supplement the existing clinical evidence for the *Neuro-Spinal Scaffold* implant. We do not anticipate reopening enrollment in The INSPIRE Study and we expect to provide additional clarity on our clinical path forward in the second quarter of 2018. We are required to obtain FDA approval before we will be permitted to resume any clinical trials with respect to *Neuro-Spinal Scaffold* implant. We cannot be certain that we will be able to define a clinical path forward, or that we will be able to raise the funds necessary for the clinical path that is required by the FDA.

Our financial statements as of September 30, 2017 were prepared under the assumption that we will continue as a going concern. At September 30, 2017, we had cash, cash equivalents, and marketable securities of $17.2 million. We estimate that our existing cash resources will be sufficient to fund our operations into the third quarter of 2018. This estimate is based on assumptions that may prove to be wrong; expenses could prove to be significantly higher, leading to a more rapid consumption of our existing resources. In particular, we may be required to undertake clinical studies that are significantly more costly that we are anticipating.

Our current cash resources will not be sufficient to complete clinical development of our *Neuro-Spinal Scaffold* implant. If we are unable to define a clinical path forward in a timely manner or in a manner that aligns with our cash resources, or it we are unable to raise capital, we may be forced to cease our operation entirely. Even if we are able to define a clinical path forward, our ability to continue as a going concern will depend on our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce or contain expenditures, and, ultimately, to generate revenue.

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

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.

If we are able to define a viable clinical path forward, we expect our expenses will increase in connection with our ongoing activities, particularly as we undertake our proposed randomized controlled trial to supplement the existing clinical evidence for the *Neuro-Spinal Scaffold* implant, and 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 definition of a viable clinical path forward with respect to our *Neuro-Spinal Scaffold* implant;
- 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;
- 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;

- 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

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be available to us on acceptable terms, or at all, and if we are not successful in raising additional capital, we may not be able to continue as a going concern.

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 $22.1 million for the nine months ended September 30, 2017. As of September 30, 2017, we had an accumulated deficit of $179.2 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;
- 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.

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

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

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

We have generated significant net operating loss carryforwards, 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 of the Internal Revenue Code of 1986, or the Code, as amended, respectively. Those sections generally restrict the use of NOLs and R&D credits after an ownership change. An ownership change occurs if, among other things, the stockholders (or specified groups of stockholders) who own or have owned, directly or indirectly, 5% or more of a corporation s common stock or are otherwise treated as 5% stockholders under Section 382 of the Code and the United States Treasury Department regulations promulgated thereunder increase their aggregate percentage ownership of that corporation s stock by more than 50 percentage points over the lowest percentage of the stock owned by these stockholders over the applicable testing period. In the event of an ownership change, Section 382 imposes an annual limitation on the amount of taxable income a corporation may offset with NOL carryforwards and Section 383 imposes an annual limitation on the amount of tax a corporation may offset with business credit (including the R&D credit) carryforwards. Any unused annual limitation may be carried over to later years until the applicable expiration date for the respective NOL or R&D credit carryforwards. We have completed several financings since our inception, which may have resulted in a change in control as defined by Sections 382 and 383 of the Code, or could result in a change in control in the future, but we have not completed an analysis of whether a limitation as noted above exists. We have not performed a Section 382 study yet, but we will complete an appropriate analysis before our tax attributes are utilized.

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 to 80% of current year taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses 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 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

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advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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

We may make acquisitions of businesses, technologies, or intellectual property rights that we believe would be necessary, useful, or complementary to our current business. Any such acquisition may require assimilation of the operations, products or product candidates, and personnel of the acquired business and the training and integration of its employees, and could substantially increase our operating costs, without any offsetting increase in revenue. 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, or HDE, pathway for the commercial sale of any product candidate, we must demonstrate through extensive preclinical testing and clinical trials that the product candidate does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Alternatively, if we were to seek premarket approval, 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 United States Food & Drug Administration, or FDA, regulatory approval process and are commercialized. Accordingly, even if we are able to obtain the requisite capital to continue to fund our development and clinical programs, we may be unable to successfully develop or commercialize our *Neuro-Spinal Scaffold* implant or any other product candidate.

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.

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Before we can obtain regulatory approval for the sale of our *Neuro-Spinal Scaffold* implant, we must define a clinical path forward and complete the clinical studies that are required as part of that clinical path. In July 2017, The INSPIRE Study of our *Neuro-Spinal Scaffold* implant was placed on hold following the third patient death in the trial. As part of the ongoing discussions with the FDA, we have proposed a randomized controlled trial to supplement the existing clinical evidence for the *Neuro-Spinal Scaffold* implant. We do not anticipate reopening enrollment in The INSPIRE Study and we expect to provide clarity on our clinical path forward in the second quarter of 2018. We are required to obtain FDA approval before we will be permitted to resume any clinical trials with respect to *Neuro-Spinal Scaffold* implant. We may not be able to define a clinical path forward successfully, or in a timely manner or that is aligned with our cash resources. If our proposed randomized controlled trial to supplement the existing clinical evidence for the *Neuro-Spinal Scaffold* implant is initiated, it may not be successfully completed or may take longer than anticipated because of any number of factors, including potential delays in the enrollment of subjects in the study, the availability of scaffolds to supply to our clinical sites, failure to demonstrate safety and probable benefit of our *Neuro-Spinal Scaffold* implant, lack of adequate funding to continue the clinical trial, or unforeseen safety issues. Enrolling patients in any 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 patients in follow-up 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 have implemented procedures in our clinical trial to limit such variations, we cannot be certain that regulatory authorities will accept the results of our clinical trials or interpret them the way that we do. Although these reversions are not believed to be related to the scaffold, we submitted information regarding these cases to the FDA for its review. In addition, we are currently in active discussions with the FDA regarding the set of clinical data that would support a future approval of the product.

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 over oversight of clinical trial sites in The INSPIRE Study. We have sought, and will continue to seek, input from the FDA regarding the scope and timing of our proposed remediation efforts. We cannot be certain that our proposed remediation efforts will be satisfactory to the FDA or 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

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our ability to obtain approval and commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, and prospects significantly.

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

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

Patient enrollment is affected by a number of factors including:

- severity of the disease, injury, or condition under investigation;
- design of the study protocol;
- size and nature of the patient population;
- eligibility criteria for and design of the study in question;
- perceived risks and benefits of the product candidate under study;
- proximity and availability of clinical study sites for prospective patients;
- availability of competing therapies and clinical studies;
- efforts to facilitate timely enrollment in clinical studies;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

For a period in 2016, as a result of an FDA pre-specified enrollment hold, we were unable to enroll patients in The INSPIRE Study pending FDA authorization to proceed with additional enrollment, which delayed our ability to open new sites and enroll patients at the pace we had anticipated. In addition, as of July 2017, we have halted enrollment in the study and do not anticipate reopening enrollment. We are in the process of discussing an additional randomized study to supplement the previously gathered data. 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 our HDE which requires us to show the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit of health outweighs the risk of injury or illness from its use. Preliminary results may not be confirmed upon full analysis of the detailed results of an early clinical trial. Product candidates in later stages of clinical development may fail to show safety and probable benefit sufficient to support intended use claims despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidates may not be sufficient to obtain regulatory approval in the United States or elsewhere. It is also possible that patients enrolled in clinical trials will experience adverse events or unpleasant side effects that are not currently part of the product candidate s profile. Because of the uncertainties associated with clinical development and regulatory approval, we cannot determine if or when we will have an approved product 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.

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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 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 HDE approval. The OPC for The INSPIRE Study is currently defined as 25% or more of the patients in the study demonstrating an improvement of at least one AIS grade by six months post-implantation. Although The INSPIRE Study is currently structured with the OPC as the primary criterion for demonstrating probable benefit, the OPC is not the only variable that the FDA would evaluate when reviewing an HDE application. Approval is not guaranteed if the OPC is met, but even if the OPC is not met, the FDA may approve a medical device if probable benefit is supported by a comprehensive review of all clinical endpoints and preclinical results, as demonstrated by the sponsor s body of evidence.

The FDA had previously recommended that we include a randomized, concurrent control arm in the study and we have proposed a randomized controlled study as part of our ongoing discussions with the FDA. In addition, as one source of comparator data, we initiated the Contemporary Thoracic SCI Registry Study, or 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 proposed randomized controlled study or the CONTEMPO Registry Study will be successfully completed. Even if we successfully complete our proposed randomized controlled 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, preliminary data from certain registries we are using in the CONTEMPO Registry Study indicate that the conversion rate may be higher than the approximately 15.5% 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 Humanitarian Use Device, or HUD, to include additional patient populations beyond our current HUD for complete spinal cord injury, or 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.

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If the FDA subsequently approves a PMA or clears a 510(k) for the HUD or another comparable device with the same indication, the FDA may withdraw the HDE. Once a comparable device becomes legally marketed through PMA approval or 510(k) clearance to treat or diagnose the disease or condition in question, there may no longer be a need for the HUD and so the HUD may no longer meet the requirements of section 520(m)(2)(B) of the Food Drug and Cosmetic Act, or 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. As explained above in the Government Regulation section, for a combination product, the FDA must determine which center or centers within the FDA will review the product candidate and under what legal authority the product candidate will be reviewed. The process of obtaining FDA marketing clearance or approval is lengthy, expensive, and uncertain, and we cannot be sure that any of our combination products, or any other products, will be cleared or approved in a timely fashion, or at all. In addition, the review of combination products is often more complex and more time consuming than the review of a product candidate under the jurisdiction of only one center within the FDA. We cannot be sure that the FDA will not select to have our combination products reviewed and regulated by only one FDA center and/or different legal authority, in which case the path to regulatory approval would be different and could be more lengthy and costly. If the FDA does not approve or clear our products in a timely fashion, or at all, our business and financial condition will be adversely affected.

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

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

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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.

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

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shipping of any product for which we obtain clearance or approval. Manufacturing may also be subject to controls by the FDA for parts of the combination products that the FDA may find are controlled by the biologics regulations.

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

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

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

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

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

- design, development, and manufacturing;
- testing, labeling, content, and language of instructions for use and storage;

- clinical trials;
- product safety;
- marketing, sales, and distribution;
- 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.

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

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

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

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

- we may not be able to demonstrate to the FDA s satisfaction that our products are safe and effective for their intended uses;
- the data from our preclinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

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

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.

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

Our 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.

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.

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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 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.

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

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

We have limited experience manufacturing our Neuro-Spinal 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.

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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 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

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

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

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

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

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

We have been, and will continue to be, dependent on third-party CROs, medical institutions, investigators, and contract laboratories to conduct certain of our laboratory testing, animal and human clinical studies. We are responsible for confirming that each of our clinical trials is conducted in accordance with our approved plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on these third parties does not relieve us of these responsibilities and requirements. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended, or terminated, and we may not be able to obtain regulatory approval or successfully commercialize our products on a timely basis, if at all, and our business, operating results, and prospects may be adversely affected.

Risks Related to Employee Matters and Managing Growth

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

We depend on our senior management as well as key scientific personnel. We have implemented restructurings that have reduced our workforce, leaving only key positions filled, and Tamara Joseph, our Senior Vice President, General Counsel and Chief Compliance Officer, will be departing effective February 7, 2018, at which point she will provide consulting services only on an as-needed basis. We have only recently

appointed an Acting Chief Executive Officer. 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 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.

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

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

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

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

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

We are subject to various environmental, health, and safety laws and regulations, including those relating to safe working conditions, laboratory, and manufacturing practices, the experimental use of animals and humans, emissions and wastewater discharges, and the use and disposal of hazardous or potentially hazardous substances used in connection with our research. Any of these laws or regulations could cause us to incur additional expense or restrict our operations. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research and development efforts.

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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, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

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

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

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

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

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

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

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

Risks Related to Investment in Our Securities

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

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

- the status, completion, and/or results of our clinical trials;
- actual or anticipated variations in our operating results;
- 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.

If we fail to meet the requirements for continued listing on the Nasdaq Global Market, our common stock could be delisted from trading, which would decrease the liquidity of our common stock and our ability to raise additional capital.

Our common stock is currently listed for quotation on the Nasdaq Global Market. We are required to meet specified financial requirements in order to maintain our listing on the Nasdaq Global Market. One such requirement is that we maintain a minimum bid price of at least $1.00 per share for our common stock. On January 23, 2018 we received a deficiency letter from the Listings Qualifications Department of the Nasdaq Stock Market notifying us that, for the last 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, or the Bid Price Rule. We have been provided an initial period of 180 calendar days, or until July 23, 2018, or the Compliance Date, to regain compliance with the Bid Price Rule. If we do not regain compliance with the Bid Price Rule by the Compliance Date, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would need to transfer the listing of our common stock to the Nasdaq Capital Market, provided that we meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards of the Nasdaq Capital Market, with the exception of its bid price requirement, or, if we fail to meet its listing requirements, the OTC Bulletin Board. Any potential delisting of our common stock from the Nasdaq Global Market would make it more difficult for our stockholders to sell our stock in the public market and would likely result in decreased liquidity and increased volatility for our common stock.

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,

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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 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.

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USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by Lincoln Park. We will receive no proceeds from the sale of shares of common stock by Lincoln Park in this offering.

We may receive up to $15,000,000 in aggregate gross proceeds under the Purchase Agreement from any sales we make to Lincoln Park pursuant to the Purchase Agreement after the date of this prospectus. We estimate that the net proceeds to us from the sale of our common stock to Lincoln Park pursuant to the Purchase Agreement will be up to $14,799,607 over an approximately 24-month period, assuming that we sell the full amount of our common stock that we have the right, but not the obligation, to sell to Lincoln Park under the Purchase Agreement, and after other estimated fees and expenses. See Plan of Distribution elsewhere in this prospectus for more information.

We currently intend to use the estimated net proceeds we receive under the Purchase Agreement to fund continued clinical development, with the remainder of any net proceeds being used for general corporate purposes.

Our management will have significant discretion and flexibility in applying the net proceeds from the Purchase Agreement. Pending the application of the net proceeds, as described above, we intend to invest the net proceeds in high-quality, short-term, interest-bearing securities.

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DILUTION

The sale of our common stock to Lincoln Park pursuant to the Purchase Agreement will have a dilutive impact on our stockholders. In addition, the lower our stock price is at the time we exercise our right to sell shares to Lincoln Park, the more shares of our common stock we will have to issue to Lincoln Park pursuant to the Purchase Agreement and our existing stockholders would experience greater dilution.

Our net tangible book value as of September 30, 2017 was $14.2 million, or $0.41 per share of common stock. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of September 30, 2017.

After giving effect to the sale of 10,700,000 shares of common stock to Lincoln Park pursuant to the Purchase Agreement at an assumed average sale price of $0.665 per share of common stock (based on the closing sale price of our common stock on January 25, 2018), our as adjusted net tangible book value as of September 30, 2017 would have been approximately $21,301,000, or $0.47 per share. This represents an immediate increase in net tangible book value of $0.06 per share to existing stockholders.

The number of shares of our common stock to be outstanding as shown above is based on 34,234,580 shares outstanding as of September 30, 2017, and excludes as of that date:

- 2,798,246 shares of our common stock issuable upon exercise of outstanding warrants, having a weighted average exercise price of $8.75 per share;

- 3,972,998 shares of our common stock issuable upon exercise of outstanding stock options, having a weighted average exercise price of $6.53 per share;

- 2,534,548 shares of our common stock reserved for future issuance under our incentive compensation plans and 401(k) plan; and

- 253,021 shares of common stock reserved for future sale under our employee stock purchase plan.

As of December 31, 2017, our 2014 Warrants were exercisable for 13,429 shares of common stock at an exercise price of $0.83 per share. The exercise price and the number of shares issuable upon exercise of the 2014 Warrants are subject to adjustment in the event of sales of our

common stock at a price per share less than the exercise price of the 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). The determination of whether common stock was sold at a price below the exercise price of the 2014 Warrants is made pursuant to a formula set forth in the 2014 Warrants. As a result of the issuance of the Commitment Shares, the exercise price of the 2014 Warrants was adjusted downwards from $0.83 to $0.70 per share and the outstanding 2014 Warrants became exercisable for 15,924 shares of common stock. Assuming that, as a result of this offering, the exercise price of the 2014 Warrants will be further adjusted downwards from $0.70 to $0.25 per share, which is the lowest price at which we may deliver a Regular Purchase Notice (as defined in the Purchase Agreement) to Lincoln Park under the Purchase Agreement, the 2014 Warrants would be exercisable for approximately 44,588 shares of common stock. In the event that the exercise price is adjusted to a price below the assumed exercise price of $0.25 per share, the number of shares of common stock for which the 2014 Warrants would be exercisable would further increase.

To the extent that outstanding options or warrants outstanding have been or may be exercised or other shares are issued, investors purchasing our common stock in this offering may experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

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LINCOLN PARK TRANSACTION

General

On January 25, 2018, we entered into the Purchase Agreement and the Registration Rights Agreement with Lincoln Park. Pursuant to the terms of the Purchase Agreement, Lincoln Park has agreed to purchase from us up to $15,000,000 of our common stock (subject to certain limitations) from time to time during the term of the Purchase Agreement. Pursuant to the terms of the Registration Rights Agreement, we have filed with the SEC the registration statement that includes this prospectus to register for resale under the Securities Act the shares that have been or may be issued to Lincoln Park under the Purchase Agreement.

Pursuant to the terms of the Purchase Agreement, at the time we signed the Purchase Agreement and the Registration Rights Agreement, we issued 429,800 Commitment Shares to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the Purchase Agreement.

We do not have the right to commence any sales to Lincoln Park under the Purchase Agreement until certain conditions set forth in the Purchase Agreement, all of which are outside of Lincoln Park s control, have been satisfied, including the registration statement that includes this prospectus being declared effective by the SEC, which we refer to as the Commencement. Thereafter, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase an initial amount of shares of our common stock upon the Commencement, as well as shares of our common stock in amounts up to 150,000 shares on any single business day from and after the Commencement, which amounts may be increased to up to 250,000 shares of our common stock depending on the market price of our common stock at the time of sale, subject to a maximum of $1,000,000 per purchase. In addition, upon notice to Lincoln Park, we may, from time to time and at our sole discretion, direct Lincoln Park to purchase additional shares of our common stock in accelerated purchases, additional accelerated purchases and/or additional purchases as set forth in the Purchase Agreement. The purchase price per share is based on the market price of our common stock at the time of sale as computed under the Purchase Agreement. Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

Under applicable rules of The Nasdaq Global Market, in no event may we issue or sell to Lincoln Park under the Purchase Agreement shares of our common stock in excess of the Exchange Cap (which is 6,852,465 shares, or 19.99% of the shares of our common stock outstanding immediately prior to the execution of the Purchase Agreement), unless (i) we obtain stockholder approval to issue shares of common stock in excess of the Exchange Cap or (ii) the average price of all applicable sales of our common stock to Lincoln Park under the Purchase Agreement equals or exceeds $0.711 per share (which represents the closing consolidated bid price of our common stock on January 24, 2018, plus an incremental amount to account for our issuance of the Commitment Shares to Lincoln Park), such that the transactions contemplated by the Purchase Agreement are exempt from the Exchange Cap limitation under applicable Nasdaq rules. In any event, the Purchase Agreement specifically provides that we may not issue or sell any shares of our common stock under the Purchase Agreement if such issuance or sale would breach any applicable rules or regulations of The Nasdaq Global Market.

The Purchase Agreement also prohibits us from directing Lincoln Park to purchase any shares of common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by Lincoln Park, would result in Lincoln Park and its affiliates exceeding the Beneficial Ownership Cap.

Purchase of Shares Under the Purchase Agreement

Regular Purchases

Under the Purchase Agreement, on any business day selected by us on which the closing sale price of our common stock is not below $0.25 (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the Purchase Agreement), we may direct Lincoln Park to purchase up to 150,000 shares of our common stock on such business day (or the purchase date), which we refer to as a Regular Purchase, provided, however, that (i) the Regular Purchase may be increased to up to 175,000 shares, provided that the closing sale price is not below $0.75 on the applicable purchase date, (ii) the Regular Purchase may be increased to up to 200,000 shares, provided that the closing sale price is not below $1.00 on the applicable purchase date, and (iii) the Regular Purchase may be increased to up to 250,000 shares, provided that the closing sale price is not below $1.50 on the applicable purchase date. In each case, the maximum amount of any single Regular Purchase may not exceed $1,000,000 per purchase. We may direct Lincoln Park to purchase shares in a Regular Purchase only if at least one business day has passed since the most recent Regular Purchase notice, as applicable, was delivered to Lincoln Park.

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The purchase price per share for each such Regular Purchase will be equal to the lower of:

- the lowest sale price for our common stock on the purchase date of such shares; and

- the arithmetic average of the three lowest closing sale prices for our common stock during the 10 consecutive business days ending on the business day immediately preceding the purchase date of such shares.

Accelerated Purchases

We may also direct Lincoln Park, on any business day on which we have properly submitted a Regular Purchase notice and the closing sale price of our common stock is not below $0.30 (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the Purchase Agreement), to purchase an additional amount of our common stock, which we refer to as an Accelerated Purchase, of up to the lesser of:

- 1,700,000 shares; and

- 30% of the aggregate shares of our common stock traded during all or, if certain trading volume or market price thresholds specified in the Purchase Agreement are crossed on the applicable Accelerated Purchase date, the portion of the normal trading hours on the applicable Accelerated Purchase date prior to such time that any one of such thresholds is crossed, which period of time on the applicable Accelerated Purchase date we refer to as the Accelerated Purchase Measurement Period .

The purchase price per share for each such Accelerated Purchase will be equal to the lower of:

- 97% of the volume weighted average price of our common stock during the applicable Accelerated Purchase Measurement Period on the applicable Accelerated Purchase date; and

- the closing sale price of our common stock on the applicable Accelerated Purchase date.

Additional Accelerated Purchases

We may also direct Lincoln Park, not later than 1:00 p.m., Eastern time, on any business day on which an Accelerated Purchase has been completed and all of the shares to be purchased thereunder have been properly delivered to Lincoln Park in accordance with the Purchase Agreement, provided that the closing price of our common stock on the business day immediately preceding such business day is not below $0.30 (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the Purchase Agreement), to purchase an additional amount of our common stock, which we refer to as an Additional Accelerated Purchase, of up to the lesser of:

- 1,700,000 shares; and

- 30% of the aggregate shares of our common stock traded during a certain portion of the normal trading hours on the applicable Additional Accelerated Purchase date as determined in accordance with the Purchase Agreement, which period of time on the applicable Additional Accelerated Purchase date we refer to as the Additional Accelerated Purchase Measurement Period.

We may, in our sole discretion, submit multiple Additional Accelerated Purchase notices to Lincoln Park prior to 1:00 p.m., Eastern time, on a single Accelerated Purchase date, provided that all prior Accelerated Purchases and Additional Accelerated Purchases (including those that have occurred earlier on the same day) have been completed and all of the shares to be purchased thereunder have been properly delivered to Lincoln Park in accordance with the Purchase Agreement.

The purchase price per share for each such Additional Accelerated Purchase will be equal to the lower of:

- 97% of the volume weighted average price of our common stock during the applicable Additional Accelerated Purchase Measurement Period on the applicable Additional Accelerated Purchase date; and

- the closing sale price of our common stock on the applicable Additional Accelerated Purchase date.

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Initial Purchase

We may also direct Lincoln Park, in our sole discretion, to purchase on the business day immediately following the date of Commencement, in one single purchase only, a number of shares of our common stock equal to the quotient obtained by dividing (i) $1,000,000 by (ii) the per share purchase price for such shares to be calculated as set forth below, for an aggregate purchase price of $1,000,000, which we refer to as the Initial Purchase.

The purchase price per share to be paid by Lincoln Park in such Initial Purchase shall be equal to the lower of:

- the closing sale price for our common stock on the date of Commencement; and

- the arithmetic average of the ten (10) closing sale prices for our common stock during the 10 consecutive business days ending on and including the date of Commencement.

Additional Purchases

From and after Commencement, we may also direct Lincoln Park, on any business day that the closing price of our common stock is not below $0.45 (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction), to purchase additional amounts of our common stock, or an Additional Purchase, provided that (i) we may direct Lincoln Park to purchase shares in an Additional Purchase only if at least 15 business days have passed since the most recent Additional Purchase, as applicable, was completed, (ii) we may direct Lincoln Park to purchase shares in an Additional Purchase only if at least 30 business days have passed since the Initial Purchase, if exercised, was completed, (iii) Lincoln Park s committed obligation under any single Additional Purchase shall not exceed $500,000, and (iv) Lincoln Park s committed obligation under all Additional Purchases shall not exceed $2,500,000 in the aggregate.

The purchase price for each such Additional Purchase shall be equal to the lower of:

- 96% of the lower of (i) the lowest sale price for our common stock on the purchase date of such shares, and (ii) the arithmetic average of the three lowest closing sale prices for our common stock during the 10 consecutive business days ending on the business day immediately preceding the purchase date of such shares; or

- $1.50 per share.

In the case of the Regular Purchases, Accelerated Purchases, Additional Accelerated Purchases, Initial Purchase and Additional Purchases, the purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction occurring during the business days used to compute the purchase price.

Other than as described above, there are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Lincoln Park.

Events of Default

Events of default under the Purchase Agreement include the following:

- the effectiveness of the registration statement of which this prospectus forms a part lapses for any reason (including, without limitation, the issuance of a stop order), or any required prospectus supplement and accompanying prospectus are unavailable for the resale by Lincoln Park of our common stock offered hereby, and such lapse or unavailability continues for a period of 10 consecutive business days or for more than an aggregate of 30 business days in any 365-day period;

- suspension by our principal market of our common stock from trading for a period of one business day;

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- the de-listing of our common stock from The Nasdaq Global Market, our principal market, provided our common stock is not immediately thereafter trading on the New York Stock Exchange, the Nasdaq Global Select Market, the Nasdaq Capital Market, the NYSE American, the NYSE Arca, the OTC Bulletin Board or OTC Markets (or nationally recognized successor thereto);

- the failure of our transfer agent to issue to Lincoln Park shares of our common stock within three business days after the applicable date on which Lincoln Park is entitled to receive such shares;

- any breach of the representations or warranties or covenants contained in the Purchase Agreement or Registration Rights Agreement that has or could have a material adverse effect on us and, in the case of a breach of a covenant that is reasonably curable, that is not cured within five business days;

- if at any time the Exchange Cap is reached, to the extent applicable;

- any voluntary or involuntary participation or threatened participation in insolvency or bankruptcy proceedings by or against us; or

- if at any time we are not eligible to transfer our common stock electronically.

Lincoln Park does not have the right to terminate the Purchase Agreement upon any of the events of default set forth above. During an event of default, all of which are outside of Lincoln Park s control, we may not direct Lincoln Park to purchase any shares of our common stock under the Purchase Agreement.

Our Termination Rights

We have the unconditional right, at any time, for any reason and without any payment or liability to us, to give notice to Lincoln Park to terminate the Purchase Agreement. In the event of bankruptcy proceedings by or against us, the Purchase Agreement will automatically terminate without action of any party.

No Short-Selling or Hedging by Lincoln Park

Lincoln Park has agreed that neither it nor any of its affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement.

Prohibitions on Variable Rate Transactions

There are no restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement or Registration Rights Agreement other than a prohibition on entering into certain equity line of credit, at-the-market or other similar offerings, as described in the Purchase Agreement.

Effect of Performance of the Purchase Agreement on Our Stockholders

All 10,700,000 shares registered in this offering which have been or may be issued or sold by us to Lincoln Park under the Purchase Agreement are expected to be freely tradable. It is anticipated that shares registered in this offering will be sold over a period of up to 24 months commencing on the date that the registration statement including this prospectus becomes effective. The sale by Lincoln Park of a significant amount of shares registered in this offering at any given time could cause the market price of our common stock to decline and to be highly volatile. Sales of our common stock to Lincoln Park, if any, will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some or none of the additional shares of our common stock that may be available for us to sell pursuant to the Purchase Agreement. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us under the Purchase Agreement may result in substantial dilution to the interests of other holders of our common stock. In addition, if we sell a substantial number of shares to Lincoln Park under the Purchase Agreement, or if investors expect that we will do so, the actual sales of shares or the mere existence of our arrangement with Lincoln Park may

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make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such sales. However, we have the right to control the timing and amount of any additional sales of our shares to Lincoln Park and the Purchase Agreement may be terminated by us at any time at our discretion without any cost to us.

Pursuant to the terms of the Purchase Agreement, we have the right, but not the obligation, to direct Lincoln Park to purchase up to $15,000,000 of our common stock, exclusive of the 429,800 Commitment Shares issued to Lincoln Park on the date of the Purchase Agreement. Depending on the price per share at which we sell our common stock to Lincoln Park pursuant to the Purchase Agreement, we may need to sell to Lincoln Park under the Purchase Agreement more shares of our common stock than are offered under this prospectus in order to receive aggregate gross proceeds equal to the $15,000,000 total commitment available to us under the Purchase Agreement. If we choose to do so, we must first register for resale under the Securities Act such additional shares of our common stock, which could cause additional substantial dilution to our stockholders. The number of shares ultimately offered for resale by Lincoln Park under this prospectus is dependent upon the number of shares we direct Lincoln Park to purchase under the Purchase Agreement.

The Purchase Agreement prohibits us from issuing or selling to Lincoln Park under the Purchase Agreement (i) shares of our common stock in excess of the Exchange Cap, unless we obtain stockholder approval to issue shares in excess of the Exchange Cap or the average price of all applicable sales of our common stock to Lincoln Park under the Purchase Agreement equal or exceed $0.711 per share, such that the transactions contemplated by the Purchase Agreement are exempt from the Exchange Cap limitation under applicable NASDAQ rules, and (ii) any shares of our common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by Lincoln Park, would exceed the Beneficial Ownership Cap.

The following table sets forth the amount of gross proceeds we would receive from Lincoln Park from our sale of shares to Lincoln Park under the Purchase Agreement at varying purchase prices:

Assumed Average Purchase Price Per Share	Number of Registered Shares to be Issued if Full Purchase (1)	Percentage of Outstanding Shares After Giving Effect to the Issuance to Lincoln Park (2)	Proceeds from the Sale of Shares to Lincoln Park Under the $15M Purchase Agreement
$ 0.25	6,422,665	15.6%	$ 1,605,666
$ 0.50	6,422,665	15.6%	$ 3,211,333
$ 0.665(3)	6,422,665	15.6%	$ 4,271,072
$ 1.00	10,270,200	22.8%	$ 10,270,200
$ 3.00	5,000,000	12.6%	$ 15,000,000
$ 5.00	3,000,000	8.0%	$ 15,000,000

(1) Although the Purchase Agreement provides that we may sell up to $15,000,000 of our common stock to Lincoln Park, we are only registering 10,700,000 shares under this prospectus which represents: (i) 429,800 shares that we already issued to Lincoln Park as a commitment fee for making the commitment under the Purchase Agreement, and (ii) an additional 10,270,200 shares which may be issued to Lincoln Park in the future under the Purchase Agreement, if and when we sell shares to Lincoln Park under the Purchase Agreement, and which may or may not cover all the shares we ultimately sell to Lincoln Park under the Purchase Agreement, depending on the purchase price per share. As a result, we have included in this column only those shares that we are registering in this offering. If we seek to issue shares of our common stock, including shares from other transactions that may be aggregated with the transactions contemplated by the Purchase Agreement under the applicable rules of The Nasdaq

Global Market, in excess of 6,852,465 shares, or 19.99% of the total common stock outstanding immediately prior to the execution of the Purchase Agreement, we may be required to seek stockholder approval in order to be in compliance with the rules of The Nasdaq Global Market.

(2) The denominator is based on 34,274,776 shares outstanding as of December 31, 2017, adjusted to include the issuance of (i) 429,800 commitment shares issued to Lincoln Park upon the execution of the Purchase Agreement, and (ii) the number of shares set forth in the adjacent column which we would have sold to Lincoln Park, assuming the purchase price in the adjacent column. The numerator is based on the number of shares

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issuable under the Purchase Agreement at the corresponding assumed purchase price set forth in the adjacent column.

(3) The closing sale price of our common stock on January 25, 2018.

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PRICE RANGE OF COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Market Information

Our common stock has been publicly traded on The Nasdaq Global Market under the symbol NVIV since April 17, 2015. From October 29, 2010 through April 16, 2015, our common stock was quoted on the OTCQB under the same symbol. The following table shows the high and low bid prices for our common stock for our two most recent fiscal years:

	High	Low
Year ended December 31, 2016		
First Quarter	$ 10.36	$ 3.50
Second Quarter	$ 7.10	$ 5.38
Third Quarter	$ 7.94	$ 5.42
Fourth Quarter	$ 6.77	$ 4.00
Year ended December 31, 2017		
First Quarter	$ 4.95	$ 3.80
Second Quarter	$ 4.30	$ 1.90
Third Quarter	$ 2.79	$ 1.10
Fourth Quarter	$ 2.25	$ 0.72
Year ended December 31, 2018		
First Quarter (through January 25, 2018)	$ 0.99	$ 0.60

On January 25, 2018, the last sale price of our common stock, as reported on The Nasdaq Global Market, was $0.665 per share.

Holders

On December 31, 2017, there were approximately 311 holders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividend Policy

We have never paid any cash dividends on our capital stock and do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain future earnings to fund ongoing operations and future capital requirements of our business. Any future determination to pay cash dividends will be at the discretion of the Board of Directors and will be dependent upon our financial condition, results of operations, capital requirements and such other factors as the Board of Directors deems relevant.

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SELECTED FINANCIAL DATA

You should read the selected financial data presented below in conjunction with the information included in the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations of this prospectus and our financial statements and the related notes included elsewhere in this prospectus. The summary financial data presented below under the heading Statements of Operations Data for the years ended December 31, 2016, 2015 and 2014 and the selected financial data presented below under the heading Balance Sheet Data as of December 31, 2016 and 2015 have been derived from our audited financial statements included elsewhere in this prospectus. The selected statement of operations data for the years ended December 31, 2013 and 2012 and the balance sheet data as of December 31, 2014, 2013 and 2012 are derived from our audited financial statements not included in this prospectus. The following selected statement of operations data for the nine months ended September 30, 2017 and 2016 and the balance sheet data as of September 30, 2017 have been derived from our unaudited financial statements included elsewhere in this prospectus. All share amounts give effect to the 1-for-4 reverse stock split of our outstanding shares of common stock that occurred on April 8, 2015.

InVivo Therapeutics Holdings Corp.

Consolidated Statement of Operations (in thousands)	Nine Months Ended September 30, (Unaudited) 2017	2016	Year Ended December 31, 2016	2015	2014	2013	2012
Operating expenses:							
Research and development	$ 9,522	$ 8,659	$ 12,557	$ 10,058	$ 10,273	$ 10,533	$ 6,376
General and administrative	10,389	8,573	11,506	12,340	7,566	8,472	6,403
Total operating expenses	19,911	17,232	24,063	22,398	17,839	19,005	12,779
Operating loss	(19,911)	(17,232)	(24,063)	(22,398)	(17,839)	(19,005)	(12,779)
Other income (expense):							
Interest income	152	133	187	60	5	15	35
Interest expense	(58)	(117)	(155)	(172)	(136)	(130)	(72)
Modification of warrants						(765)	
Derivatives gain (loss)	(2,264)	(788)	593	(10,804)	(376)	(18,871)	17,480
Other income (expense), net	(2,170)	(772)	625	(10,916)	(507)	(19,751)	17,443
Net income (loss)	$ (22,081)	$ (18,004)	$ (23,438)	$ (33,314)	$ (18,346)	$ (38,756)	$ 4,664
Net income (loss) per share, basic	$ (0.68)	$ (0.59)	$ (0.76)	$ (1.26)	$ (0.83)	$ (2.10)	$ 0.30
Net income (loss) per share, diluted	(0.68)	(0.59)	$ (0.76)	$ (1.26)	$ (0.83)	$ (2.10)	$ 0.26
Weighted average number of common shares outstanding, basic	32,516,190	30,687,263	31,025,585	26,461,374	22,080,761	18,497,922	15,806,725
Weighted average number of common shares outstanding, diluted	32,516,190	30,687,263	31,025,585	26,461,374	22,080,761	18,497,922	17,979,855

Condensed Consolidated Balance Sheet (in thousands)	Nine Months Ended September 30, (Unaudited) 2017	2016	As of December 31, 2015	2014	2013	2012
Cash, cash equivalents and marketable securities	$ 17,168	$ 33,041	$ 20,194	$ 13,459	$ 13,980	$ 12,825
Working capital	14,435	29,005	17,427	6,169	12,334	(3,221)
Total assets	18,596	34,784	21,792	16,693	17,096	16,062
Long-term liabilities	776	987	1,551	1,991	1,938	1,581
Derivative warrant liability	41	1,314	1,907	7,224		14,585

Accumulated deficit	(179,243)	(157,007)	(133,569)	(100,255)	(81,909)	(43,153)
Stockholder s equity (deficit)	14,251	28,949	16,929	5,918	12,890	(2,310)

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SUPPLEMENTARY FINANCIAL INFORMATION

Supplementary Quarterly Financial Data (Unaudited In thousands)

	Quarter Ended		
	September 30, 2017	June 30, 2017	March 31, 2017
Operating expenses:			
Research and development	$ 2,928	$ 3,211	$ 3,384
General and administrative	3,388	3,715	3,285
Total operating expenses	6,316	6,926	6,669
Operating loss	(6,316)	(6,926)	(6,669)
Other income (expense):			
Interest income	43	52	57
Interest expense	(18)	(20)	(20)
Derivatives gain (loss)	(3,059)	554	241
Other income (expense), net	(3,034)	586	278
Net loss	$ (9,350)	$ (6,340)	$ (6,391)

	Quarter Ended			
	December 31, 2016	September 30, 2016	June 30, 2016	March 31, 2016
Operating expenses:				
Research and development	$ 3,900	$ 3,294	$ 2,795	$ 2,568
General and administrative	2,932	2,584	2,991	2,999
Total operating expenses	6,832	5,878	5,786	5,567
Operating loss	(6,832)	(5,878)	(5,786)	(5,567)
Other income (expense):				
Interest income	47	50	36	54
Interest expense	(31)	(32)	(29)	(63)
Derivatives gain (loss)	1,381	(336)	595	(1,047)
Other income (expense), net	1,397	(318)	602	(1,056)
Net loss	$ (5,435)	$ (6,196)	$ (5,184)	$ (6,623)

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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 prospectus and with our historical consolidated financial statements, and the related notes thereto, included in our Annual Report on Form 10-K for the year ended December 31, 2016, or the 2016 Annual Report. The management s discussion and analysis contains forward-looking statements within the meaning of the safe harbor provisions under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements include statements made regarding our commercialization strategy, future operations, cash requirements and liquidity, capital requirements, and other statements on our business plans and strategy, financial position, and market trends. In some cases, you can identify forward-looking statements by terms such as may, might, will, should, believe, plan, intend, anticipate, target, estimate, expect, and other similar expressions. These forward-looking statements are subject to risks and uncertainties that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements in this prospectus, including factors such as our limited operating history and history of net losses; our ability to raise substantial additional capital to finance our planned operations and to continue as a going concern; our ability to define a viable clinical path forward following our ongoing discussions with the FDA, including our ability to commence a randomized clinical trial to support our existing HDE application; our ability to execute our strategy and business plan; our ability to obtain regulatory approvals for our current and future product candidates, including our Neuro-Spinal Scaffold implant; our ability to successfully commercialize our current and future product candidates, including our Neuro-Spinal Scaffold implant; the progress and timing of our current and future development programs; our ability to successfully re-open, enroll and complete clinical trials and obtain and maintain regulatory approval of our current and future product candidates; our ability to protect and maintain our intellectual property and licensing arrangements; our reliance on third parties to conduct testing and clinical trials; market acceptance and adoption of our products; our ability to promote, manufacture, and sell our current and future products, either directly or through collaborative and other arrangements with third parties; our ability to attract and retain key personnel; and other factors detailed under Risk Factors in this prospectus. 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 prospectus, except as required by law.

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

Overview

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

intended to treat acute SCI. 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.

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Our Clinical Program

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

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.

The INSPIRE Study

Our *Neuro-Spinal Scaffold* implant has been studied in The **INSPIRE** Study: **In**Vivo Study of Probable Benefit of the *Neuro-**Spi**nal Scaffold* for Safety and Neurologic **Re**covery in Subjects with Complete Thoracic AIS A Spinal Cord Injury, under an Investigational Device Exemption application for the treatment of neurologically complete thoracic traumatic acute SCI. We commenced an FDA-approved pilot study in 2015 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 remained in follow-up and had 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 are in ongoing discussions with the FDA and have proposed a randomized controlled trial to supplement the existing clinical evidence for the *Neuro-Spinal Scaffold* implant that we obtained from The INSPIRE Study. We do not anticipate reopening enrollment in The INSPIRE Study. We expect to provide additional clarity on our clinical path forward in the second quarter of 2018.

The purpose of The INSPIRE 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 SCI. The primary endpoint was defined as the proportion of patients achieving an improvement of at least one American Spinal Injury Association Impairment Scale, or 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 are in follow-up and have reached the six-month primary endpoint visit. Of these 16, seven had

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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. Two of the seven patients who improved and were assessed to have AIS B SCI at the six-month primary endpoint were later assessed to have improved to AIS C SCI at the 12 and 24-month visits, respectively. 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 subjects was then assessed at the six-month visit to have improved again to AIS B and the other remained AIS A. Given that the study has been on hold since July 2017 and that we are discussing an additional study with the FDA, we do not plan to reopen enrollment. As a result, 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 have proposed a randomized controlled trial 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 will utilize existing databases and registries to develop a historical comparator that, to the extent possible, matches patients to those patients enrolled in The INSPIRE Study. The CONTEMPO Registry Study is designed to provide comprehensive natural history benchmarks for The INSPIRE Study results that include SCI patients with similar baseline characteristics treated since 2006. The CONTEMPO Registry Study includes data from the Christopher & Dana Reeve Foundation North American Clinical Trials Network Registry, as well as the Model Systems Registry and the European Multicenter Study about Spinal Cord Injury. We anticipate that there will be between 100 to 200 patients in the CONTEMPO Registry Study. We have submitted a protocol for the CONTEMPO Registry Study to the FDA. We cannot be certain what additional information or studies will be required by the FDA to approve our HDE submission.

Although The INSPIRE Study is currently structured with the OPC as the primary component for demonstrating probable benefit, the OPC is not the only variable that the FDA would evaluate when reviewing a future HDE application. Approval is not guaranteed if the OPC is met, and even if the OPC is not met, the FDA may approve a medical device if probable benefit is supported by a comprehensive review of all clinical endpoints and preclinical results, as demonstrated by the sponsor s body of evidence.

Although we continue discussions with FDA regarding the appropriate supporting clinical data, we have also begun the process of submitting the marketing application for the product to the FDA. 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 modules, which are individual sections of the HDE submission, on a rolling basis. Following the submission of each module, the FDA reviews and provides feedback, typically within 90 days, allowing the applicant to receive feedback and potentially resolve any deficiencies during the review process. Upon receipt of the final module, which constitutes the complete HDE submission, the FDA makes a filing decision which may trigger the review clock for an approval decision. We submitted the first module in March 2017 and received feedback in June 2017. We are working on responses to the FDA s questions and plan to submit an updated preclinical module in 2018. The HDE submission will not be complete until the manufacturing and clinical modules are also submitted.

Completion of strategic restructuring

In August 2017, we announced a strategic restructuring and we completed a reduction in force eliminating approximately 39% of our workforce. See Note 13 in the accompanying notes to the condensed consolidated financial statements for additional information.

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.

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

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

Results of Operations

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

Research and Development Expenses

Research and development expenses consisted primarily of expenses related to contract research organizations and clinical sites, professional services, and payroll. Research and development expenses for the three months ended September 30, 2017 were $2.9 million, a decrease of $366,000 (or 11.1%) compared to the three months ended September 30, 2016. The decrease in research and development expenses for the three months ended September 30, 2017 is partially attributable to a decrease in clinical trial costs of $372,000 due to a decrease in patient enrollment in The INSPIRE Study. The decrease is also due to decreases in stock-based compensation expense of $310,000 and lab related expenses of $130,000, offset in part by increases in compensation-related expenses (including severance) of $219,000 and intellectual property costs of $180,000.

General and Administrative Expenses

General and administrative expenses consisted primarily of payroll, rent, and professional services. General and administrative expenses for the three months ended September 30, 2017 were $3.4 million, an increase of $804,000 (or 31.1%) compared to the three months ended September 30, 2016. The increase in general and administrative expenses for the three months ended September 30, 2017 is attributable to increases in compensation-related expenses of $97,000, share-based compensation expense of $166,000, consulting and professional fees of $153,000, legal costs of $276,000, and facilities costs of $96,000.

Other Income and Expense

Other income/expense for the three months ended September 30, 2017 was $3.0 million, which was comprised of interest income of $43,000, interest expense of $18,000, and a derivative loss of $3.1 million due primarily to the impact of the August 2017 warrant exchange. Other expense for the three months ended September 30, 2016 was $318,000, which was comprised of interest income of $50,000, interest expense of $32,000, and a derivative loss of $336,000.

Comparison of the Nine Months Ended September 30, 2017 and 2016

Research and Development Expenses

Research and development expenses consisted primarily of expenses related to contract research organizations and clinical sites, professional services, and payroll. Research and development expenses for the nine months ended September 30, 2017 were $9.5 million, an increase of $863,000 (or 10.0%) compared to the nine months ended September 30, 2016. The increase in research and development expenses for the nine months ended September 30, 2017 is partially attributable to an increase in clinical trial costs of $346,000 due to an increase in patient enrollment in The INSPIRE Study and the opening of additional clinical trial sites. The increase is also due to increases in consulting and professional fees of $801,000, recruiting costs of $127,000, and intellectual property

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costs of $168,000, offset in part by decreases in stock-based compensation expense of $143,000, facilities allocation of $101,000, and contract services and lab expenses of $328,000.

General and Administrative Expenses

General and administrative expenses consisted primarily of payroll, rent, and professional services. General and administrative expenses for the nine months ended September 30, 2017 were $10.4 million, an increase of $1.8 million (or 21.2%) compared to the nine months ended September 30, 2016. The increase in general and administrative expenses for the nine months ended September 30, 2017 is attributable to increases in compensation-related expenses (including severance) of $774,000, consulting and professional fees of $388,000, facilities allocation of $251,000, legal costs of $255,000, and share-based compensation expense of $187,000. These increases were offset in part by a decrease in recruiting and relocation costs of $166,000.

Other Income and Expense

Other income/expense for the nine months ended September 30, 2017 was $2.2 million, which was comprised of interest income of $152,000, interest expense of $58,000, 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. Other expense for the nine months ended September 30, 2016 was $772,000, which was comprised of interest income of $133,000, interest expense of $117,000, and a derivative loss of $788,000.

Comparison of the Years Ended December 31, 2016 and 2015 (in thousands, except share and per share amounts)

Research and Development Expenses

Research and development expenses increased by $2,499 to $12,557 for the year ended December 31, 2016 from $10,058 for the year ended December 31, 2015. This increase is primarily attributable to an increase in clinical trial costs of $811 due to an increase in the number of patients in The INSPIRE Study and the opening of additional clinical trial sites, and higher contract services costs of $439 associated with research development initiatives. The increase is also due to compensation-related expenses of $656, intellectual property costs of $229, consulting fees of $110, recruiting costs of $102, and packaging and lab-related expenses of $123.

General and Administrative Expenses

General and administrative expenses decreased by $834 to $11,506 for the year ended December 31, 2016 from $12,340 for the year ended December 31, 2015. This decrease in general and administrative expenses is attributable to a decrease in legal expenses of $1,737 as well as decreases in public and investor relations costs of $116 and overhead expense of $93. These decreases are partially offset by increases in

compensation-related expenses of $342, stock-based compensation expense of $292, convention and meeting costs of $178, recruiting related costs of $162, insurance expense of $118, and consulting fees of $54.

Interest Income

Interest income increased by $127 to $187 for the year ended December 31, 2016 from $60 for the year ended December 31, 2015. This increase is due to a higher average balance of funds in our short-term investments.

Interest Expense

Interest expense decreased by $17 to $155 for the year ended December 31, 2016 from $172 for the year ended December 31, 2015. This decrease in interest expense is primarily due to lower average borrowings.

Derivatives Gain (Loss)

The derivatives gain for the year ended December 31, 2016 is $593 compared to a loss of $10,804 for the year ended December 31, 2015. The gain of $593 for the year ended December 31, 2016 reflects the decrease in the

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fair value of our derivative warrant liability due primarily to the decrease in the fair value of the underlying common stock, as well as the decreasing term to expiration of the warrants. In 2015, the loss was driven primarily by an increase in the value of our common stock.

Comparison of the Years Ended December 31, 2015 and 2014 (in thousands, except share and per share amounts)

Research and Development Expenses

Research and development expenses decreased by $215 to $10,058 for the year ended December 31, 2015 from $10,273 for the year ended December 31, 2014. After adjusting for the $621 insurance settlement related to business interruption, research and development expenses were $10,894 for 2014. The decrease in adjusted research and development expenses for 2015 of $836 was primarily attributable to decreases in consulting costs of $612, testing costs of $375, packaging and lab supplies of $359, compensation-related expense attributable to the 2014 reduction in force of $564, and other various expenses of $338. These reductions were partly offset by higher clinical trial costs of $729, stock compensation expense of $147, and bonus expense of $536. Bonus expense was higher in 2015 compared to 2014 due to the fact that in 2014 the accrual, which related to the 2013 bonus accrual, was reversed because of the Company s decision not to pay out 2013 bonuses.

General and Administrative Expenses

General and administrative expenses increased by $4,774 to $12,340 for the year ended December 31, 2015 from $7,566 for the year ended December 31, 2014. This increase in general and administrative expenses for 2015 was primarily attributable to increases in legal costs of $1,361, related to the Securities and Exchange Commission (SEC) and Massachusetts Securities Division of the Secretary of the Commonwealth of Massachusetts inquiries as well as the Securities Class Action lawsuit, stock compensation expense of $1,789, investor relation expense and NASDAQ listing fees of $425, Board and audit fees of $251, consulting costs of $387, and other various expenses of $561.

Interest Income

Interest expense increased by $55 to $60 for the year ended December 31, 2015 from $5 for the year ended December 31, 2014. This increase was due to interest earned on our short-term investments.

Interest Expense

Interest expense increased by $36 to $172 for the year ended December 31, 2015 from $136 for the year ended December 31, 2014. This increase in interest expense was primarily due to the amortization of the premium or discount values of our short-term investments compared to the maturity value.

Derivatives Gain (Loss)

Derivative losses decreased by $10,428 to a loss of $10,804 for the year ended December 31, 2015 from a loss of $376 for the year ended December 31, 2014. The loss of $10,804 for the year ended December 31, 2015 reflects the increase in the fair value of our derivative warrant liability, which was due primarily to the increase in the fair value of the underlying common stock, the decreasing term to expiration of the warrants as well as the exercise of approximately 78% of the outstanding warrants during 2015.

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, 2017, we had total assets of $18.6 million, total liabilities of $4.3 million, and total stockholders equity of $14.3 million. For the nine months ended September 30, 2017, we recorded a net loss of $22.1 million and our accumulated deficit as of September 30, 2017 was $179.2 million.

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We do not expect to be profitable in the next several years, but rather expect to incur additional operating losses. We have limited liquidity and capital resources and must obtain significant additional capital resources in order to fund our operations and sustain our product development efforts, for acquisition of technologies and intellectual property rights, for preclinical and clinical testing of our anticipated products, for pursuing regulatory approvals, for the acquisition of capital equipment, laboratory and office facilities, for establishment of production capabilities, for selling, general, and administrative expenses, and for other working capital requirements. We also expect that we will need to raise additional capital through a combination of equity offerings, debt financings, other third party funding, marketing and distribution arrangements and/or other collaborations, strategic alliances, and licensing arrangements.

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

On August 10, 2017, we entered into exchange agreements with certain holders of our warrants, dated May 9, 2014, to exchange such warrants for shares of common stock. We issued an aggregate of 2,021,419 shares of common stock to the warrant holders in exchange for their warrants to purchase an aggregate of 577,548 shares of common stock. The warrants exchanged in this transaction were subsequently cancelled and terminated. As a result of our issuance of common stock in exchange for certain of the warrants, the per share exercise price of the remaining warrants, dated May 9, 2014, was adjusted downwards from $3.87 per share to $0.83 per share and additional warrants were issued such that the remaining warrants were exercisable for an aggregate of 48,507 shares of common stock. We did not receive any cash proceeds from the warrant exchanges.

In the fourth quarter of 2017, we entered into warrant cancellation agreements with certain remaining holders of our warrants, dated May 9, 2014, to cancel and terminate such warrants for cash consideration. As of December 31, 2017, the remaining warrants were exercisable for an aggregate of 13,429 shares of common stock. As a result of the issuance of the Commitment Shares to Lincoln Park on January 25, 2018, the exercise price of the 2014 Warrants was further adjusted downwards from $0.83 to $0.70 per share and the outstanding 2014 Warrants became exercisable for 15,924 shares of common stock.

Given our development plans, we estimate cash resources will be sufficient to fund our operations into the third quarter of 2018. This estimate is based on assumptions that may prove to be wrong; expenses could prove to be significantly higher, leading to a more rapid consumption of our existing resources.

Net cash used in operating activities for the nine months ended September 30, 2017 was $15.6 million as compared to net cash used in operating activities of $12.5 million for the nine months ended September 30, 2016. The $3.1 million increase in net cash used in operating activities for the nine months ended September 30, 2017 as compared to the same period in the prior year was primarily due to a $4.1 million increase in our net loss, changes in working capital of $666,000, and a $1.7 million increase in non-cash items primarily driven by the impact of the August 2017 warrant exchange and the change in fair value of our derivative warrant liability.

We also have significant commitments that will require the use of cash in operating activities in future periods, including our obligations under current operating leases. At September 30, 2017, our total committed lease obligations amounted to $11.6 million including total commitments due for the remainder of 2017 under our operating leases of $314,000.

In August 2017, we announced a reduction in our workforce of approximately 39%. All affected employees received severance pay and outplacement assistance. As a result of the reduction in force and associated costs, we estimate savings of approximately $7.3 million in annual operating expenses, with one-time severance and related costs of $697,000. Of these one-time severance and related costs, approximately $348,000 was paid through September 30, 2017.

Net cash provided by investing activities for the nine months ended September 30, 2017 was $10.8 million attributable primarily to sales of marketable securities of $19.1 million, partially offset by purchases of marketable securities of $8.3 million. This compares to net cash used in investing activities of $7.0 million for the nine months

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ended September 30, 2016 attributable primarily to purchases of marketable securities of $8.0 million, partially offset by sales of marketable securities of $1.1 million.

Net cash used in financing activities was $238,000 for the nine months ended September 30, 2017 consisting of loan repayments of $315,000, partially offset by proceeds from the exercise of stock options and Employee Stock Purchase Plan issuances of $77,000. This compares to net cash provided by financing activities of $29.9 million for the nine months ended September 30, 2016 consisting of proceeds from our March 2016 offering of $29.9 million, ESPP issuances of $91,000, and stock option exercises of $191,000, offset in part by loan repayments of $294,000.

We intend to pursue opportunities to obtain additional financing in the future through equity and/or debt financings. We have filed with the United States Securities and Exchange Commission, or SEC, and the SEC declared effective, a shelf registration statement which permits us to issue up to $150 million worth of common stock, warrants, or units consisting of common stock and warrants. Under this effective shelf registration, we have the flexibility to issue registered securities, from time to time, in one or more separate offerings or other transactions with the size, price, and terms to be determined at the time of issuance. Registered securities issued using this shelf registration statement may be used to raise additional capital to fund our working capital and other corporate needs, for future acquisitions of assets, programs or businesses, and for other corporate purposes.

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

Off-Balance Sheet Arrangements

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

Contractual Obligations

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

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QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. We do not use derivative financial instruments for speculative or trading purposes. Our interest-earning assets consisted of cash, cash equivalents and marketable securities. Our interest income is subject to changes as a result of potential changes in the general level of interest rates, primarily U.S. interest rates. Due to the short-term duration and low risk profile of our cash, cash equivalents and short-term investments, an immediate 10.0% change in interest rates would not have a material effect on the fair value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our cash, cash equivalents and short-term investments. At December 31, 2017, our cash equivalents were primarily composed of money market accounts comprised of high-quality, short-term securities that are issued or guaranteed by the U.S. government or by U.S. government agencies and instrumentalities.

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BUSINESS

Business Overview

We are a research and clinical-stage biomaterials and biotechnology company with a focus on treatment of spinal cord injuries, or SCIs. Our mission is to redefine the life of the SCI patient, and we seek to develop treatment options intended to provide meaningful improvement in patient outcomes following SCI. Our approach to treating acute SCIs is based on our investigational *Neuro-Spinal Scaffold* implant, a bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord and is intended to treat acute SCI. 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.

Market Opportunity

Our clinical program is intended to address the lack of successful treatments for SCIs, which can lead to permanent paralysis, sensory impairment, and autonomic (bowel, bladder, and sexual) dysfunction. The current management of acute SCI is a surgical approach consisting of spine stabilization and an external decompression procedure of uncertain value. We believe the market opportunity for our *Neuro-Spinal Scaffold* implant is significant. It is estimated that approximately 282,000 people are currently living in the United States with paralysis due to SCI (chronic SCI), and approximately 15,000 individuals in the United States will become fully or partially paralyzed each year (acute SCI). We are pursuing regulatory approval from the U.S. Food and Drug Administration, o FDA, through the Humanitarian Device Exemption, or HDE, pathway. When this pathway was initiated for the *Neuro-Spinal Scaffold* implant, it was limited to populations of 4,000 or less patients per year. We were granted a Humanitarian Use Device, or HUD, designation for the *Neuro-Spinal Scaffold* implant, which includes thoracic and cervical patients afflicted with complete (no motor or sensory function in the lowest sacral segments) SCI, such as paraplegia or tetraplegia, and excludes gunshot or other penetrating wounds. Recently, the 21st Century Cures Act 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 SCI patients, i.e., incomplete (partial sensory or sensory/motor function below the injury site, including the lowest sacral segments) SCI patients. Future products, which may include use of stem cells or drug ingredients, may enable the treatment of a broader population such as patients with chronic paralysis and would require separate regulatory approval.

Since 1973, the National Spinal Cord Injury Statistical Center, or NSCISC, at the University of Alabama has been commissioned by the U.S. government to maintain a national database of SCI statistics. The financial impact of SCIs, as reported by the NSCISC, is substantial. Direct costs, which include hospital and medical expenses, modification of the home, and personal assistance, are highest in the first year after injury. According to the fact sheet published in 2016 by NSCISC titled Spinal Cord Injury Facts and Figures at a Glance , (i) during the first year, average cost of care ranges from $347,896 to $1,065,980, depending on the severity of the injury, (ii) the net present value, or NPV, to maintain a quadriplegic injured at age 25 for life is $4,729,788, and (iii) the NPV to maintain a paraplegic injured at age 25 for life is $2,312,846. These costs place a tremendous financial burden on families, insurance providers, and government agencies. Moreover, despite such a significant financial investment, the patient often remains disabled for life because current medical interventions address only the symptoms of SCI rather than the underlying neurological cause. We believe our approach could represent an important advance in the treatment of SCIs.

The American Spinal Injury Association, or ASIA, in collaboration with the International Spinal Cord Society, or ISCoS, has developed a neurologic examination tool for assessing SCI known as the International Standards for Neurological Classification of Spinal Cord Injury, or ISNCSCI. Results of the ISNCSCI examination are used to determine the ASIA Impairment Scale, or AIS, classification.

Patients with complete SCI are classified as AIS A. Patients with incomplete SCI, who have partial sensory and/or motor function below the level of injury, including the lowest sacral segments, are classified as AIS B (partial sensory function), AIS C (partial sensory and motor function), or AIS D (partial sensory and increased motor function, i.e., can move at least half of the muscles against gravity). Patients who have a complete return of sensory and motor function are classified as AIS E.

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These classifications are based upon the ISNCSCI examination in which an examiner performs a neurologic examination to assess sensory function of the entire body and motor function of the upper and lower extremities.

Our Clinical Program

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

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 the FDA, or growth factors. We expect the *Neuro-Spinal Scaffold* implant to be regulated by the FDA as a Class III medical device.

Preclinical and Non-clinical Studies relating to the Neuro-Spinal Scaffold

SCI can result in permanent paralysis, sensory impairment, and autonomic (bowel, bladder, and sexual) dysfunction. These functional deficits result from damage to or loss of cells (neurons and glia) in the affected region of the spinal cord, either from the initial mechanical trauma or through secondary mechanisms that persist for several weeks. The ability of potential treatments for SCI to mitigate loss of function or promote recovery can be evaluated with non-clinical models using different species and different methods of inducing SCI. In our preclinical studies, we utilized rat, non-human primate, and pig models because each exhibits a pattern of neuropathology following SCI that is similar to human SCI. Hemicordectomy injury models, in which sections of spinal cord are surgically removed, are useful in the evaluation of treatment strategies that involve device implantation. Unilateral hemicordectomy models preserve function on one side of the cord, resulting in improved recovery of bladder and bowel function. We, therefore, evaluated the bioresorbable polymer scaffold device in both rats and non-human primates with unilateral hemicordectomy injury. Because most human SCIs are non-penetrating contusion injuries resulting from rapid compression of spinal tissue by intrusion of bone or disc material following mechanical disruption of the vertebral column, we also evaluated the bioresorbable polymer scaffold device in rat and pig models of spinal contusion injury.

Our first non-clinical study was conducted by founding scientists of our wholly-owned subsidiary in rats with surgically induced unilateral spinal cord hemicordectomy injury. This study (see Teng, Y. D., et al., *Functional recovery following traumatic spinal cord injury mediated by a unique polymer scaffold seeded with neural stem cells*, Proceedings of the National Academy of Sciences 99, pg. 3024-3029, 2002) demonstrated the baseline safety and efficacy of porous, biodegradable scaffolds fabricated from PLGA-PLL polymer. Subsequently, the safety and

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efficacy of implantation of the bioresorbable polymer scaffold device was evaluated in rats with spinal cord contusion injury. Initial studies suggest that 24 hours after contusion injury was an appropriate time for device implantation based on both histological evaluation and *ex vivo* Magnetic Resonance Imaging, or MRI, techniques. Based on these results, we conducted larger rat contusion studies in our laboratory. We evaluated functional recovery with the 21-point Basso, Beattie, and Bresnahan, or BBB, locomotor rating scale to assess open field locomotion. In the first model, the BBB score was not improved by the scaffold device. However, implantation of the bioresorbable polymer scaffold device into the necrotic zone of the injured spinal cord resulted in appositional healing and tissue remodeling that preserved spinal cord architecture. Morphometric analysis of spinal sections stained with hematoxylin & eosin revealed that non-implanted rats with contusion injury developed large cavities surrounded by a thin rim of spared white matter. In contrast, rats treated with the implanted bioresorbable polymer scaffold device demonstrated decreased cavity volume along with increased amounts of spared and remodeled tissue at the lesion epicenter. Immunofluorescence labeling within the remodeled tissue identified high levels of laminin, an absence of GFAP-positive astrocytes, as well as beta-3 tubulin positive axons. This indicated that the bioresorbable polymer scaffold device supports tissue formation and remodeling favorable for axon regrowth. Following spinal contusion injury, myelin-producing nerve cells called Schwann cells arise from either injured nerve roots or endogenous sources within the central nervous system. The Schwann cells migrate into the injury region, promoting axonal growth and remyelinating segmentally demyelinated axons. In rats implanted with the bioresorbable polymer scaffold device, we observed that Schwann cell myelination was extensive within preserved penumbra white matter and also that Schwann cell myelination was detected within the remodeled tissue. These results indicate that implantation of the bioresorbable polymer scaffold device in the acutely injured rat spinal cord can provide the benefit of preserving spinal cord architecture through reduced cavitation, and promotion of white matter sparing and tissue remodeling supportive to axon sprouting and spinal cord activity.

The spinal cord anatomy of non-human primates is very similar to that of humans. We performed a series of studies in African green monkeys to evaluate the bioresorbable polymer scaffold device in a non-human primate. Our first study in African green monkeys established that unilateral thoracic hemicordectomy SCI (a new model in this species) produced a consistent functional deficit, and we observed a consistently positive response to scaffold implantation (see Pritchard, et al., *Establishing a model spinal cord injury in the African green monkey for the preclinical evaluation of biodegradable polymer scaffolds seeded with human neural stem cells*, Journal of Neuroscience Methods 188, pg. 258- 269, 2010). We then conducted two larger studies evaluating the safety and efficacy of the bioresorbable polymer scaffold device in the African green monkey (see Slotkin, J.R., Pritchard, et al., *Biodegradable scaffolds promote tissue remodeling and functional improvement in non-human primates with acute spinal cord injury*. Biomaterials, 123, pp. 63-76). The extent and time course of functional recovery in biopolymer implant-treated primates was assessed with video capture and KinemaTracer evaluation of locomotor behavior with synchronous electromyography recording along with locomotor observation rating. When the results of these two studies were combined and analyzed together, we found that implantation of the bioresorbable polymer scaffold device resulted in an increase in remodeled tissue in the region of the hemicordectomy compared to non-implant controls, and improved recovery of locomotion in subjects with full unilateral hemicordectomy lesions (see Slotkin, J.R., et al., *Biodegradable scaffolds promote tissue remodeling and functional improvement in non-human primates with acute spinal cord injury*, Biomaterials, 123, pg. 63-76, 2017).

The pig has been used as a large animal model of spinal cord contusion injury due to similarities in size and structure to the human spinal cord. We evaluated the surgical feasibility of implanting the bioresorbable polymer scaffold device in a spinal cord after a contusion injury in a pig model. Severe contusion injuries were created in Gottingen pigs with a weight drop apparatus. At approximately 4, 6, and 24 hours after contusion injury, the pigs underwent the bioresorbable polymer scaffold device surgical implantation procedure. At each time point, a large volume of necro-hemorrhagic fluid and debris rapidly effluxed from the injury site, releasing built-up pressure and resulting in a substantial cavity in the center of the spinal cord. Increased spinal tissue pressure after contusion injury results in reduced blood perfusion and ischemia in damaged spinal tissue, and is an important contributor to the pathophysiology of SCI. As part of our study, we placed bioresorbable polymer scaffold devices into the resulting contusion-induced spinal cord cavity. We measured intraspinal pressure (using catheter pressure probes) at the contusion epicenter in the pigs before, during, and after the surgical procedure. As expected, contusion injury elevated intraspinal tissue pressure compared to normal values. Surgical implantation of the bioresorbable polymer scaffold device resulted in a return of intraspinal tissue pressure to physiologically normal levels.

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Taken together, these non-clinical studies in two rat SCI models, the African green monkey unilateral hemicordectomy injury model, and the pig contusion injury model, demonstrate that the bioresorbable polymer scaffold device, surgically implanted at the epicenter of the wound after an acute SCI, acts by appositional healing to help spare spinal cord tissue, decrease post-traumatic cyst formation, decrease spinal cord tissue pressure, and promote tissue remodeling supportive to axon sprouting and spinal cord activity.

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: **In**Vivo Study of Probable Benefit of the *Neuro-**Spi**nal Scaffold* for Safety and Neurologic **Re**covery in Subjects with Complete Thoracic AIS A Spinal Cord Injury, under an Investigational Device Exemption application for the treatment of neurologically complete thoracic traumatic acute SCI. We commenced an FDA-approved pilot study in 2015 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 remained in follow-up and had 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 are in ongoing discussions with the FDA and have proposed a randomized controlled trial to supplement the existing clinical evidence for the *Neuro-Spinal Scaffold* implant that we obtained from The INSPIRE Study. We do not anticipate reopening enrollment in The INSPIRE Study. We expect to provide additional clarity on our clinical path forward in the second quarter of 2018.

The purpose of The INSPIRE 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 SCI. The primary endpoint was defined as the proportion of patients achieving an improvement of at least one American Spinal Injury Association Impairment Scale, or 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 are in follow-up and 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. Two of the seven patients who improved and were assessed to have

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improved to AIS C SCI at the 12 and 24-month visits, respectively. 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. Given that the study has been on hold since July 2017 and that we are discussing an additional study with the FDA, we do not plan to reopen enrollment. As a result, 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 have proposed a randomized controlled trial 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 will utilize existing databases and registries to develop a historical comparator that, to the extent possible, matches patients to those patients enrolled in The INSPIRE Study. The CONTEMPO Registry Study is designed to provide comprehensive natural history benchmarks for The INSPIRE Study results that include SCI patients with similar baseline characteristics treated since 2006. The CONTEMPO Registry Study includes data from the Christopher & Dana Reeve Foundation North American Clinical Trials Network Registry, as well as the Model Systems Registry and the European Multicenter Study about Spinal Cord Injury. We anticipate that there will be between 100 to 200 patients in the CONTEMPO Registry Study. We have submitted a protocol for the CONTEMPO Registry Study to the FDA. We cannot be certain what additional information or studies will be required by the FDA to approve our HDE submission.

As noted above, we are continuing to discuss with the FDA the set of data that will be used to support HDE approval in the future. While we expect The INSPIRE Study to serve as one source of data, we no longer expect to complete full enrollment of that study. In addition, although The INSPIRE Study is currently structured with the OPC as the primary component for demonstrating probable benefit, the OPC is not the only variable that the FDA would evaluate when reviewing a future HDE application. Approval is not guaranteed if the OPC is met, and even if the OPC is not met, the FDA may approve a medical device if probable benefit is supported by a comprehensive review of all clinical endpoints and preclinical results, as demonstrated by the sponsor s body of evidence.

Although we continue discussions with FDA regarding the appropriate supporting clinical data, we have also begun the process of submitting the marketing application for the product to the FDA. 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 modules, which are individual sections of the HDE submission, on a rolling basis. Following the submission of each module, the FDA reviews and provides feedback, typically within 90 days, allowing the applicant to receive feedback and potentially resolve any deficiencies during the review process. Upon receipt of the final module, which constitutes the complete HDE submission, the FDA makes a filing decision which may trigger the review clock for an approval decision. We submitted the first module in March 2017 and received feedback in June 2017. We are working on responses to the FDA s questions and plan to submit an updated preclinical module in 2018. The HDE submission will not be complete until the manufacturing and clinical modules are also submitted.

Intellectual Property

We rely on a combination of patents, licenses, trade secrets, and non-disclosure agreements to develop, protect, and maintain our intellectual property. Our patent portfolio includes patents and patent applications. We seek to develop or obtain intellectual property that we believe might be useful or complementary with our products and technologies, including by way of licenses or acquisitions of other companies or intellectual property from third parties.

We hold an exclusive worldwide license to a broad suite of patents co-owned by BCH and MIT covering the use of a wide range of polymers to treat SCI, and to promote the survival and proliferation of human stem cells in the spinal cord, or the BCH License. Issued patents and pending patent applications licensed under the BCH License cover the technology underlying our *Neuro-Spinal Scaffold* implant and the use of a wide range of biomaterial scaffolding for treating SCI by itself or in combination with drugs, growth factors, or human stem cells. The BCH License covers eight issued United States patents and 16 issued international patents expiring between

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2018 and 2027, and one pending United States patent application and seven pending international patent applications.

The BCH License has a term of 15 years from the effective date of July 2, 2007, or as long as the life of the last expiring patent right under the license, whichever is longer, unless terminated earlier by BCH. In connection with our acquisition of the BCH License, we submitted to a 5-year development plan to BCH and MIT that includes certain targets and projections related to the timing of product development and regulatory approvals. We are required to either meet the stated targets and projections in the plan, or notify BCH and revise the plan. BCH has the right to terminate the BCH License for failure by us to either meet the targets and projections in the plan or our failure to submit an acceptable revision to the plan within a 60-day cure period after notification by BCH that we are not in compliance with the plan. We are currently in compliance with the development plan.

We have the right to sublicense the patents covered by the BCH License, and have full control and authority over the development and commercialization of any products that use the licensed technology, including clinical trial design, manufacturing, marketing, and regulatory filings. We also own the rights to the data generated pursuant to the BCH License, whether generated by us or a sublicensee. We have the first right of negotiation with BCH and MIT for a 30-day period to any improvements to the intellectual property covered by the BCH License.

We are required to pay certain fees and royalties under the BCH License. We paid an initial fee upon execution of the BCH License and are required to pay an amendment fee if we expand the field of use under the BCH License. We are also required to make milestone payments upon completing various phases of product development, including upon (i) filing with the FDA of the first investigational new drug application and IDE application for a product that uses the licensed technology; (ii) enrollment of the first patient in Phase II testing for a product that uses the licensed technology; (iii) enrollment of the first patient in Phase III testing for a product that uses the licensed technology; (iv) FDA approval of the first new drug application or related application for a product that uses the licensed technology, and (v) first market approval in any country outside the United States for a product that uses the licensed technology. Each year prior to the release of a licensed product, we are also required to pay a maintenance fee for the BCH License. Further, we are required to make ongoing payments based on any sublicenses we grant to manufacturers and distributors. Following commercialization, we are required to make ongoing royalty payments equal to a percentage in the low single digits of net sales of any product that uses the licensed technology.

In addition to the rights we license under the BCH license, we have additional rights relating to the *Neuro-Spinal Scaffold* implant. Together with MIT, we co-own patent application No. U.S. 14/232,525 (Poly((lactic-co-glycolic acid)-b-lysine) and process for synthesizing a block copolymer of PLGA and PLL- (poly-e-cbz-l-lysine)).

Government Regulation

The testing, manufacturing, and potential labeling, advertising, promotion, distribution, import, and marketing of our products are subject to extensive regulation by governmental authorities in the United States and in other countries. In the United States, the FDA, under the Public Health Service Act, the Federal Food, Drug and Cosmetic Act, or FDCA, and their implementing regulations, regulates biologics and medical device products. In addition, our products under development are subject to extensive regulation by other U.S. federal and state regulatory bodies and comparable authorities in other countries. To ensure that medical products distributed domestically are safe and effective for their intended use, the FDA and comparable authorities in other countries have imposed regulations that govern, among other things, the following activities that we or our partners perform or will perform:

- product design and development;

- product testing;

- product manufacturing;

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- product labeling;
- product storage;
- premarket clearance, approval, or CE marking of products;
- advertising and promotion;
- product marketing, sales, and distribution; and
- post-market surveillance reporting, including reporting of death or serious injuries.

The labeling, advertising, promotion, marketing, and distribution of biopharmaceuticals, or biologics, and medical devices also must be in compliance with the FDA requirements which include, among others, standards and regulations for off-label promotion, industry sponsored scientific and educational activities, promotional activities involving the internet, and direct-to-consumer advertising. In addition, the Federal Trade Commission, or FTC, also regulates the advertising of many medical devices. The FDA and the FTC have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing us to correct deviations from regulatory standards and enforcement actions that can include seizures, injunctions, and criminal prosecution. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims.

The FDA has broad premarket, post-market, and regulatory enforcement powers. As with medical devices, manufacturers of biologics and combination products are subject to unannounced inspections by the FDA to determine compliance with applicable regulations, and these inspections may include the manufacturing facilities of some of our subcontractors. Failure by manufacturers or their suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities. Potential FDA enforcement actions include:

- warning letters, fines, injunctions, consent decrees, and civil penalties;
- unanticipated expenditures to address or defend such actions;

- customer notifications for repair, replacement, or refunds;

- recall, detention, or seizure of our products;

- operating restrictions or partial suspension or total shutdown of production;

- refusing or delaying our requests for 510(k) clearance on HDE or premarket approval applications, or PMA, of new products or modified products;

- operating restrictions;

- withdrawing 510(k) clearances on HDE or PMA approvals that have already been granted;

- refusal to grant export approval for our products; or

- criminal prosecution.

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FDA Regulation Medical Device Products

FDA s Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either prior 510(k) clearance or prior premarket approval from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risk are placed in either Class I or II, which requires the manufacturer to submit to the FDA a premarket notification which must be cleared by the FDA before the medical device may be distributed commercially. This process is known as 510(k) clearance. Most Class I devices are exempt from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III, requiring premarket approval or approval of an HDE. We expect the *Neuro-Spinal Scaffold* implant will be regulated by the FDA as a Class III medical device.

Premarket Approval Pathway

A PMA must be submitted if the device cannot be cleared through the 510(k) process. A PMA must be supported by extensive data including, but not limited to, technical, preclinical, and other non-clinical, clinical, and manufacturing and labeling information to demonstrate to the FDA s satisfaction the safety and effectiveness of the device for its intended use.

If the FDA determines that a PMA submission is sufficiently complete, the FDA will accept the application for filing and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the accepted application, although, generally, review of the application can take between one and three years, and it may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulations. New PMAs or PMA supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device s indication for use, manufacturing process, labeling, and design. Premarket approval supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA, and may not require as extensive clinical data or the convening of an advisory panel.

Humanitarian Device Exemption

Alternatively, a Class III device may qualify for FDA approval to be distributed under an HDE rather than a PMA. For a device to be eligible for an HDE, it must be first designated by the FDA as an HUD intended to benefit patients in the treatment or diagnosis of a disease or condition that affects fewer than 8,000 individuals in the United States per year (increased by the 21st Century Cures Act from 4,000 to 8,000). The HDE pathway also requires that there must be no other comparable device available to provide therapy for this condition. 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. In addition, an HUD may only be used in facilities that have established a local institutional review board, or IRB, to supervise clinical testing of devices, and after an IRB has approved the use of the device to treat or diagnose the specific disease.

In addition, 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, a product 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

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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. We expect our *Neuro-Spinal Scaffold* implant may meet the eligibility criteria to be sold for a profit.

Clinical Trials

Clinical trials are almost always required to support a PMA or HDE application. If the device presents a significant risk to human health as defined by the FDA, the FDA requires the device sponsor to submit an IDE to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device, in which case an IDE approval from the FDA would not be required, although the clinical trial would need to meet other requirements including IRB approval. Clinical trials for a significant risk device may begin once an IDE is approved by the FDA and the appropriate IRB at each clinical trial site. Future clinical trials may require that we obtain an IDE from the FDA prior to commencing any such clinical trial and that the trial be conducted with the oversight of an IRB at the clinical trial site.

Our clinical trials must be conducted in accordance with FDA regulations and federal and state regulations concerning human subject protection, including informed consent and healthcare privacy. A clinical trial may be suspended by the FDA or at a specific site by the relevant IRB at any time for various reasons, including a belief that the risks to the trial participants outweigh the benefits of participation in the clinical trial. Even if a clinical trial is completed, the results of our clinical testing may not demonstrate the safety and efficacy of the device, or may be equivocal or otherwise not be sufficient for us to obtain approval of our product.

Pervasive and Continuing FDA Regulation

After a device is placed on the market, numerous regulatory requirements continue to apply. These include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;

- Quality System Regulation, or QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the manufacturing process;

- labeling regulations and FDA prohibitions against the promotion of products for uncleared or unapproved indications or other off-label uses;

- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;

- approval of product modifications that affect the safety or effectiveness of one of our approved devices;

- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;

- post-approval restrictions or conditions, including post-approval study commitments;

- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;

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- the FDA s recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;

- regulations pertaining to voluntary recalls; and

- notices of corrections or removals.

We and any third-party manufacturers that we use must register with the FDA as medical device manufacturers and must obtain all necessary state permits or licenses to operate our business. As manufacturers, we and any third-party manufacturers that we use are subject to announced and unannounced inspections by the FDA to determine our compliance with quality system regulation and other regulations. We have not yet been inspected by the FDA. We believe that we are in substantial compliance with quality system regulation and other regulations.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees, and civil penalties;

- unanticipated expenditures to address or defend such actions;

- customer notifications for repair, replacement, or refunds;

- recall, detention, or seizure of our products;

- operating restrictions or partial suspension or total shutdown of production;

- refusing or delaying our requests for 510(k) clearance on HDE or PMA of new products or modified products;

- operating restrictions;
- withdrawing 510(k) clearances on HDE or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Regulatory Pathway for the Neuro-Spinal Scaffold Implant

We expect the *Neuro-Spinal Scaffold* implant will be regulated by the FDA as a Class III medical device. The FDA granted HUD designation for our *Neuro-Spinal Scaffold* implant in 2013 for use in complete SCI (defined as less than 4,000 patients per year), thus allowing us to potentially qualify for FDA approval under an HDE. In 2015, we received conditional approval from the FDA to convert our ongoing pilot study into a pivotal probable benefit study. Full approval of such conversion was subsequently granted in January 2016. We are currently in discussion with the FDA regarding the clinical data package that would support future HDE approval for the *Neuro-Spinal Scaffold* implant.

In the future, if our *Neuro-Spinal Scaffold* implant is approved via either the PMA or HDE pathway, modifications or enhancements that could significantly affect the safety or effectiveness of the device or that constitute a major change to the intended use of the device will require new PMA or HDE application and approval.

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Other changes may require a supplement or other change notification that must be reviewed and approved by the FDA. Modified devices for which a new PMA or HDE application, supplement, or notification is required cannot be distributed until the application is approved by the FDA. An adverse determination or a request for additional information could delay the market introduction of new products, which could have a material adverse effect on our business, financial condition, and results of operations. We may not be able to obtain PMA or HDE approval in a timely manner, if at all, for the *Neuro-Spinal Scaffold* implant or any future devices or modifications to *Neuro-Spinal Scaffold* implant or such devices for which we may submit a PMA or HDE application.

European Economic Area, or the EEA

Sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. In order to market our products outside the United States, we must obtain regulatory approvals or CE Certificates of Conformity and comply with extensive safety and quality regulations. The time required to obtain approval by a foreign country or to obtain a CE Certificate of Conformity may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ. In the EEA, we are required to obtain Certificates of Conformity before drawing up a European Commission, or EC, Declaration of Conformity and affixing the CE mark to our medical devices. Many other countries, such as Australia, India, New Zealand, Pakistan and Sri Lanka, accept CE Certificates of Conformity or FDA clearance or approval although others, such as Brazil, Canada and Japan, require separate regulatory filings. We have not yet applied for a CE Mark for the *Neuro-Spinal Scaffold* implant.

If any of our products has been CE marked and placed on the market in the EEA, we would need to comply with a number of regulatory requirements relating to:

- registration/notification of medical devices in individual EEA countries;
- pricing and reimbursement of medical devices;
- establishment of post-marketing surveillance and adverse event reporting procedures;
- Field Safety Corrective Actions, including product recalls and withdrawals;
- marketing and promotion of medical devices; and
- interactions with physicians.

Failure to comply with these requirements at such time could result in enforcement measures being taken against us by the competent authorities of the EEA countries. These can include fines, administrative penalties, compulsory product withdraws, injunctions, and criminal prosecution. Such enforcement measures would have an adverse effect on our capacity to market our products in the EEA and, consequently, on our business and financial position. Such failures could also lead to cancelation, suspension, or variation of our CE Certificates of Conformity by the relevant Notified Body, which is an organization designated by the competent authorities of an EEA country to conduct conformity assessments.

Further, the advertising and promotion of our products in the EEA is subject to regulatory directives concerning misleading and comparative advertising, and unfair commercial practices, as well as other national legislation in the individual EEA countries governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

Research and Development Expenditures

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 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. Our research and development expenditures, which include research and

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development related to our product candidates, were approximately $11.1 million in 2017 and $12.6 million and $10.1 million in 2016 and 2015, respectively.

Competition

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 obtaining regulatory approval for products, production and manufacturing, and sales and marketing of 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 compete effectively, 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 any of 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.

Manufacturing

We have developed a proprietary manufacturing process to build our *Neuro-Spinal Scaffold* implant. We manufacture our implants following FDA regulations for design controls using two fully operational manufacturing cleanrooms located at our facility in Cambridge, Massachusetts. These two cleanrooms are validated to ISO 14644-1 Class ISO-7 (Class 10-K) and Class ISO-8 (Class 100k) cleanroom standards, respectively. In addition, the manufacturing process contains numerous quality control steps including in-process and final inspection. Currently, we are working with two vendors for our critical raw materials; however, these materials are also available from other vendors. We are currently manufacturing our *Neuro-Spinal Scaffold* implant to support the proposed randomized controlled clinical trial. As we move toward preparing for commercialization, we intend to be compliant with all applicable regulations on a country specific basis.

Sales and Marketing

If we obtain approval from the FDA, or another foreign regulatory body, to commercialize our products, we plan to establish a direct sales force to sell our products to major markets in the United States, and we may sell direct or through distributors in major foreign markets. We anticipate the direct sales force, once and if established, would focus its efforts on maximizing revenue through product training, placement, and support. We would also seek to establish strong relationships with neurosurgeons, orthopedic spine surgeons, and trauma surgeons, and would expect to provide a high level of service for any of our approved products including providing on-site assistance and service during procedures. In

addition, we expect to implement medical education programs intended for outreach to practitioners in physical medicine and rehabilitation centers and patient advocacy groups. We may also seek corporate partners with expertise in commercialization.

Compliance with Environmental, Health and Safety Laws

In addition to the FDA regulations discussed above, we are also subject to evolving federal, state, and local environmental, health, and safety laws and regulations. In the past, compliance with environmental, health, and safety laws and regulations has not had a material effect on our capital expenditures. We believe that we comply in all material respects with existing environmental, health, and safety laws and regulations applicable to us.

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Segment and Geographic Information

Operating segments are identified as components of an enterprise about which separate, discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions regarding resource allocation and assessing performance. To date, we have viewed our operations and managed our business as principally one operating segment, which is developing and commercializing biopolymer scaffolding devices for the treatment of SCIs. As of December 31, 2017, 2016, and 2015, all of our assets were located in one location in the United States.

Employees

As of December 31, 2017, we had 16 employees. None of our employees is represented by a labor union and we consider our employee relations to be good. We also utilize a number of consultants to assist with research and development and regulatory activities. We believe that our future success will depend in part on our continued ability to attract, hire, and retain qualified personnel.

Description of Properties

We lease approximately 26,150 square feet of office, laboratory, and manufacturing space in Cambridge, Massachusetts, which is used primarily for corporate, manufacturing, and research and development functions. The lease commenced in November 2011, and is for an initial term of six years and three months, with one five-year extension exercisable by us. On August 21, 2017, the Company exercised its option for the five-year extension on the Cambridge Lease. The five-year renewal lease term commences on November 1, 2018 and ends on October 31, 2023. We believe this facility is adequate to meet our current needs and that additional space could be available on commercially reasonable terms as needed.

Legal Proceedings

In November 2013, we filed a lawsuit against Francis Reynolds, our former Chairman, Chief Executive Officer and Chief Financial Officer, in Middlesex Superior Court, Middlesex County, Massachusetts (*InVivo Therapeutics Holdings Corp. v. Reynolds, Civil Action No. 13-5004*). The complaint alleges breaches of fiduciary duties, breach of contract, conversion, misappropriation of corporate assets, unjust enrichment, and corporate waste, and seeks monetary damages and an accounting. The lawsuit involves approximately $500,000 worth of personal and/or exorbitant expenses that we allege Mr. Reynolds inappropriately caused us to pay while he was serving as our Chief Executive Officer, Chief Financial Officer, President, and Chairman of our Board of Directors. On December 6, 2013, Mr. Reynolds answered the complaint, and filed counterclaims against us and our Board of Directors. The counterclaims allege two counts of breach of contract, two counts of breach of the covenant of good faith and fair-dealing, and tortious interference with a contract, and seek monetary damages and a declaratory judgment. The counterclaims relate to Mr. Reynolds s allegations that we and our Board of Directors interfered with the performance of his duties under the terms of his employment agreement, and that Mr. Reynolds was entitled to additional shares upon the exercise of certain stock options that he did not receive. On January 9, 2014, we, along with the directors named in the counterclaims, filed our answer 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. Renoylds. 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. Renoylds claims is the equivalent of 47,864 shares of common stock, but dismissed all other claims asserted by Mr. Reynolds. Trial is scheduled to begin on June 16, 2018.

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

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MANAGEMENT

Our Board currently consists of six directors serving on a classified board, consisting of three classes. The directors in each class serve a three-year term. The terms of each class expire at successive annual meetings so that the stockholders elect one class of directors at each annual meeting. Directors appointed due to an increase in the size of the Board may be filled by the Board for a term of office continuing only until the next election of directors by the Company s stockholders. Our directors and executive officers as of December 31, 2017 are as follows:

NAME	AGE	CURRENT POSITION
Richard Toselli	60	Acting Chief Executive Officer
Christopher McNulty	41	Chief Financial Officer
Pamela Stahl	52	Chief Commercial Officer
Tamara Joseph (1)	55	Senior Vice President, General Counsel and Chief Compliance Officer
Christina Morrison	51	Director
C. Ann Merrifield	66	Director, Chair of the Board
Jeffrey S. Hatfield	59	Director
Daniel R. Marshak	60	Director
Kenneth DiPietro	59	Director
Richard J. Roberts	74	Director

(1) Ms. Joseph s employment with us will terminate effective February 7, 2018.

Biographical and certain other information concerning our executive officers and directors is set forth below.

Richard Toselli, 60, has served as the Acting Chief Executive Officer since December 2017. Prior to being appointed Acting Chief Executive Officer, Dr. Toselli served as our Chief Medical Officer since July 2017. Before joining the Company, Dr. Toselli served as the Chief Medical Officer for Cochlear Limited, a medical device company, from June 2016 until March 2017. Prior to that, Dr. Toselli served at Sanofi, a pharmaceutical company, from July 2012 to June 2016 in various levels of increasing responsibility, including Vice President of Global Medical Affairs Immunology and Inflammation, Biologics Division; Vice President of Global Medical Affairs and Head of the Biosurgery Discovery Performance Unit; and Vice President of Global Medical Affairs, Biosurgery. Before his time at Sanofi, he served as Chief Medical/Technology Officer for Covidien Public Limited Company (now Medtronic Public Limited Company), a medical device company, and earlier held the position of Vice President of Evidence-Based Medicine for the device sector at Johnson & Johnson, a medical device, pharmaceutical and consumer packaged goods manufacturing company. Prior to that, Dr. Toselli held various roles at DePuy Synthes Spine, Inc., a medical device company, including Director of Medical Affairs, Worldwide Vice President of Research and Development, and Worldwide Vice President of Clinical Evidence and External Relations. Dr. Toselli holds a bachelor of arts from Providence College, his medical degree from Brown University, and a masters of business administration from the UNC s Kenan-Flagler Business School. Dr. Toselli is a board-certified neurological surgeon.

Christopher McNulty, 41, has served as our Chief Financial Officer since March 2017. Prior to being appointed Chief Financial Officer, Mr. McNulty served as our Senior Vice President, Business Development & Investor Relations. In that role, he has led the Company s business development and partnering activities as well as corporate communications, including investor relations and public relations. From June 2014 to August 2015, he served as the Company s Vice President, Business Development and Investor Relations, and from November 2013 to

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July 2014, he served as the Company s Vice President, Business Development. Prior to joining the Company, Mr. McNulty served at Repligen Corporation, a pharmaceutical and bioprocessing company, from 2010 to 2013, most recently as Senior Director of Business Development. From 2009 to 2010, he was Director of Corporate Development at Seventh Sense Biosystems, Inc., a medical device company. From 2006 to 2009, Mr. McNulty served at Genzyme Corporation, a biotechnology company, most recently as Associate Director of Alliance Management and Business Development. Before joining Genzyme, Mr. McNulty held technical roles at Transform Pharmaceuticals, Inc. from 2000 to 2004 and at Cereon Genomics, LLC from 1998 to 2000. Mr. McNulty received his B.S. and M.Eng. degrees in electrical engineering and computer science from the Massachusetts Institute of Technology. He also holds an M.B.A. from Harvard Business School.

Pamela J. Stahl, 52, has served as our Chief Commercial Officer since September of 2016. Before joining our company, Ms. Stahl served as Chief Executive Officer, Community Health Plan of Wisconsin at UnitedHealthcare from December of 2014 to September 2016. While at UnitedHealthcare she was responsible for the largest Medicaid business in the state, providing healthcare benefits and services for over 160,000 Wisconsin residents. Ms. Stahl s career at UnitedHealthcare spanned 11 years during which she held a number of executive level positions that included leading corporate Consumer Strategy, establishing the Women s Health Line of Service, reorganizing and leading Sales Operations and Organizational Effectiveness for key accounts and small business, and leading Consumer and Physician Marketing. Prior to UnitedHealthcare, Ms. Stahl worked for Orphan Medical, Inc. from October 2001 until January 2006 as Vice President, Sales and Commercial Operations. Before that, she was Vice President of Sales and Marketing for American TeleCare, Inc. Ms. Stahl worked at AstraZeneca from 1992-2000 and held various leadership positions including Regional Sales Director, Product Optimization Leader for Prilosec®, Customer Unit Director, Account Team Leader, and Regional Marketing Manager. She started her career at Merck & Co., Inc. as a Sales Representative and Regional Sales Trainer. Ms. Stahl received a B.A. in Biology from St. Olaf College.

Tamara Joseph, 55, has served as our Senior Vice President, General Counsel and Chief Compliance Officer since March 2014, after beginning to work as an independent consultant to our company in September 2013. Ms. Joseph was appointed as an independent director of the public health non-profit PHFE in February 2013. She is the incoming Vice Chair of PHFE s Board of Directors and is a member of its Audit Committee and its Governance and Nominating Committee. She previously served as Senior Vice President, General Counsel of Cubist Pharmaceuticals, Inc. from April 2008 to October 2012, where she was responsible for the legal, compliance, risk management and government affairs departments. Prior to that, she served as Executive Vice President, General Counsel of Mayne Pharma Ltd., from 2006 to 2008. Before that, Ms. Joseph served as Vice President, General Counsel of Transkaryotic Therapies, Inc., and from 1998 to 2005, Ms. Joseph led the Biogen Idec Inc. legal department s operations outside the United States as Vice President, International Legal. Ms. Joseph began her legal career as a litigator with Fried, Frank, Harris, Shriver & Jacobson and later with Morrison & Foerster. Ms. Joseph has an A.B. in Economics from Duke University, a J.D. from University of Michigan Law School, an LLM degree in European Community Law from the College of Europe in Belgium and an LLM degree in Civil Law from the University of Paris.

Christina Morrison, 51, has served as a director of our company since June 2016. Ms. Morrison most recently served as the Senior Vice President of Finance of Aramark, a foodservice, facilities and uniform services provider, from June 2013 until July 2016. Prior to joining Aramark, Ms. Morrison was Senior Vice President of Business and Financial Planning at Merck & Co., Inc., a publicly traded pharmaceutical company, from November 2009 to June 2013. Before that, Ms. Morrison spent five years at Wyeth Pharmaceuticals, a publicly traded pharmaceutical

company, serving in a number of leadership roles including Senior Vice President and Chief Financial Officer of the pharmaceutical division. Ms. Morrison holds an M.B.A. from the Tuck School of Business at Dartmouth College and a B.S. in Economics from the Wharton School at the University of Pennsylvania. Ms. Morrison brings to our Board significant financial experience and a decade of experience in the pharmaceutical industry.

C. Ann Merrifield, 66, has served as the Chair of the Board since December 2017 and has been a director of our company since November 2014. She also serves as a director of Flexion Therapeutics, a public biotechnology company and Juniper Pharmaceuticals, a specialty pharmaceutical company. Ms. Merrifield most recently served as President, Chief Executive Officer, and a director of PathoGenetix, Inc., a genomics company focused on developing an automated system for rapid bacterial identification, from 2012 until July 2014 when the company filed for Chapter 7 bankruptcy. Prior to then, she spent 18 years at Genzyme Corporation, serving in a number of

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leadership roles including President of Genzyme Biosurgery, President of Genzyme Genetics and Senior Vice President, Business Excellence. Ms. Merrifield also serves as trustee and director on several boards including Partners Continuing Care, the post-acute care services division of Partners HealthCare; the YMCA of Greater Boston; and MassMutual Premier, MML, and Select/MML II Funds. She holds a B.A. in zoology and a Master of Education from the University of Maine, and an M.B.A. from the Tuck School of Business at Dartmouth College. Ms. Merrifield brings to our Board an invaluable amount of experience and expertise over her long career in the life sciences industry.

Jeffrey S. Hatfield, 59, has been a director of our company since November 2016. Mr. Hatfield has served as Chief Executive Officer of Zafgen, Inc. since October 2017. Previously, he served as President, Chief Executive Officer and Board Member of Vitae Pharmaceuticals, Inc., a pharmaceutical company, from March 2004 until September 2016, when Allergan Plc entered into a definitive agreement to purchase Vitae Pharmaceuticals. Prior to joining Vitae Pharmaceuticals, Mr. Hatfield worked at Bristol-Myers Squibb, a biopharmaceutical company, which he joined in 1985. While at Bristol-Myers Squibb, Mr. Hatfield held a variety of executive positions, including Senior Vice President of Bristol-Myers Squibb s Virology and Immunology Divisions from 2000 to 2004; President and General Manager, Canada from 1997 to 2000; and Vice President, U.S. Managed Health Care from 1996 to 1997. In 2014, Mr. Hatfield became a director of Ambit Biosciences, a biopharmaceutical company. Mr. Hatfield holds an M.B.A. from The Wharton School, University of Pennsylvania and received a bachelor s degree in Pharmacy from Purdue University. Mr. Hatfield brings to our Board extensive experience in general management and over 30 years of experience in the biopharmaceutical industry.

Daniel R. Marshak, Ph.D., 60, has been a director of our company since September 2014. He most recently served as Senior Vice President and Chief Scientific Officer for PerkinElmer, Inc., a human and environmental health company, until September 2014. Prior to joining PerkinElmer in 2006, Dr. Marshak was Vice President and Chief Technology Officer, Biotechnology, for Cambrex Corporation. Dr. Marshak has received numerous awards for scientific and academic achievements and is named as inventor on six issued U.S. patents. He currently serves on the International Society for Stem Cell Research Global Advisory Council and served on its board of directors from July 2008 to June 2014. Dr. Marshak is the author of more than 100 scientific publications, including one textbook, and has been the editor of five monographs. He recently held an appointment as Adjunct Associate Professor at the Johns Hopkins University School of Medicine and previously taught graduate biochemistry as an Assistant Professor at the State University of New York. Dr. Marshak received his B.A. degree in biochemistry and molecular biology from Harvard University, and he holds a Ph.D. in biochemistry and cell biology from The Rockefeller University. Dr. Marshak brings to our Board extensive industry experience and a deep understanding of the science and technology behind our business.

Kenneth DiPietro, 59, has been a director of our company since December 2012. Mr. DiPietro has served as Executive Vice President, Human Resources of Biogen, Inc., a publicly-traded biotechnology company, from January 2012 until May 2017. Mr. DiPietro joined Biogen from Lenovo Group, where he served as Senior Vice President, Human Resources from May 2005 until June 2011. From 2003 to 2005, he served as Corporate Vice President, Human Resources at Microsoft Corporation, and as Vice President, Human Resources at Dell Inc. from 1999 to 2002. Prior to that, he spent 17 years at PepsiCo, serving in a range of human resource and general management positions. Mr. DiPietro holds a B.S. degree in Industrial and Labor Relations from Cornell University. As a human resources senior executive, Mr. DiPietro brings broad cultural transformation, organizational development and corporate re-engineering experience to our Board.

Richard J. Roberts, Ph.D., 74, has been a director of our company since October 2010 and a director of InVivo Therapeutics Corporation, our wholly-owned subsidiary, since November 2008. Dr. Roberts initially joined InVivo Therapeutics Corporation s Scientific Advisory Board in June 2007 and continued as a member of our Scientific Advisory Board. He has served as Chief Scientific Officer at New England Biolabs, a life sciences company, since February 2007. Dr. Roberts was awarded the 1993 Nobel Prize in Physiology of Medicine along with Phillip Allen Sharp for the discovery of introns in eukaryotic DNA and the mechanism of gene-splicing. He holds a B.Sc. in Chemistry and a Ph.D. in Organic Chemistry from the University of Sheffield, U.K. Dr. Roberts brings the Board his significant experience and understanding of the science and technology involved in our business.

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Director Independence

Rule 5605 of the Nasdaq Listing Rules requires a majority of a listed company s board of directors to be comprised of independent directors within one year of listing. In addition, the Nasdaq Listing Rules require that, subject to specified exceptions, each member of a listed company s audit, compensation and nominating and corporate governance committees be independent, that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act and that compensation committee members also satisfy heightened independence requirements contained in the Nasdaq Listing Rules as well as Rule 10C-1 under the Exchange Act. Under Nasdaq Rule 5605(a)(2), a director will only qualify as an independent director if, in the opinion of our Board, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the Board, or any other Board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. When determining the independence of the members of our compensation committee under the heightened independence requirements contained in the Nasdaq Listing Rules and Rule 10C-1 under the Exchange Act, our Board is required to consider all factors specifically relevant to determining whether a director has a relationship with us that is material to that director s ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (1) the source of compensation of that director, including any consulting, advisory or other compensatory fee paid by us to that director; and (2) whether that director is affiliated with our company, a subsidiary of our company or an affiliate of a subsidiary of our company.

Our Board has reviewed the composition of our Board and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our Board has determined that each of our directors is an independent director as defined under Rule 5605(a)(2) of the Nasdaq Listing Rules.

Our Board also determined that Ms. Morrison, Mr. Hatfield, Dr. Marshak, and Ms. Merrifield, who comprise our audit committee, and Mr. DiPietro, Mr. Hatfield, Dr. Marshak and Dr. Roberts, who comprise our compensation committee, satisfy the independence standards for such committees established by the SEC and the Nasdaq Listing Rules, as applicable. In making such determinations, our Board considered the relationships that each such non-employee director has with our company and all other facts and circumstances our Board deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director.

Board Committees

The Board has designated three principal standing committees: the Audit Committee, the Nominating and Corporate Governance Committee, and the Compensation Committee.

Audit Committee

The Audit Committee assists the Board in fulfilling its responsibilities concerning our financial reporting and internal controls. The Audit Committee facilitates open communication among the Audit Committee, the Board, our independent auditor, and management. The Audit Committee discusses with management and our independent auditor the financial information developed by us, our systems of internal controls

and our audit process. The Audit Committee is solely and directly responsible for appointing, evaluating, retaining, and, where necessary, terminating the engagement of our independent auditor. The independent auditor meets with the Audit Committee (both with and without the presence of our management) to review and discuss various matters pertaining to the audit, including our financial statements and its report on the Company s financial statements and internal controls, as well as the scope and terms of the work of our independent auditor and its recommendations concerning the financial practices, controls, procedures and policies employed by our company. The current members of our Audit Committee are Ms. Morrison (Chairwoman), Mr. Hatfield, Dr. Marshak, and Ms. Merrifield. The Audit Committee held four meetings in 2017.

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The Audit Committee pre-approves all audit services to be provided to us by our independent auditor and all other services (including reviewing, attestation and non-audit services) to be provided to us by the independent auditor.

The Audit Committee is also charged with establishing procedures for (i) the receipt, retention, and treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters; and (ii) the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters. The Audit Committee reviews and oversees all related party transactions on an ongoing basis. The Audit Committee is authorized, without further action by the Board, to engage independent professional advisers and counsel as it deems necessary or appropriate to carry out its responsibilities. The Board has adopted a written charter for the Audit Committee, which is reviewed annually and a copy of which is available on the Corporate Governance page of the Investor Relations section of our website at www.invivotherapeutics.com.

The Board has determined that Ms. Morrison is an audit committee financial expert, as defined in Item 407(d)(5) of Regulation S-K.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee is charged with the responsibility of reviewing our corporate governance policies, overseeing the annual review of succession planning by the Board and with proposing potential director nominees to the Board for consideration. The Board has adopted a written charter for the Nominating and Corporate Governance Committee, which is reviewed annually and a copy of which is available on the Corporate Governance page of the Investor Relations section of our website at www.invivotherapeutics.com.

The current members of our Nominating and Corporate Governance Committee are Ms. Merrifield (Chairwoman), Mr. DiPietro, Dr. Roberts and Ms. Morrison. The Nominating and Corporate Governance Committee held four meetings in 2017.

Compensation Committee

The Compensation Committee reviews and recommends compensation arrangements for our directors, management, and employees and also assists the Board in reviewing and approving matters such as company benefits and insurance plans, including monitoring the performance thereof, as discussed in more detail below under Compensation Discussion and Analysis. The Board has adopted a written charter for the Compensation Committee, which is reviewed annually and a copy of which is available on the Corporate Governance page of the Investor Relations section of our website at www.invivotherapeutics.com.

The Compensation Committee is authorized under its charter to retain consultants to assist it in the evaluation of executive compensation and to approve the fees and other retention terms for its consultants. The Compensation Committee has retained Pearl Meyer & Partners (Pearl Meyer) as a compensation consultant to review our compensation programs and provide advice to the Compensation Committee with respect to executive compensation. Pearl Meyer does not provide any other services to InVivo. The Committee annually reviews the independence of the consultant s work under rules adopted by the SEC and NASDAQ and found no conflicts. As appropriate, the Compensation Committee also

looks to our human resources department to support the Compensation Committee in its work and to provide necessary information.

The current members of our Compensation Committee are Mr. DiPietro (Chairman), Mr. Hatfield and Drs. Marshak and Roberts. The Compensation Committee held four meetings in 2017.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics, as amended, that applies to all employees, officers, and directors of our company, including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. Our Code of Business Conduct and Ethics

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is available on the Corporate Governance page of the Investor Relations section of our website at www.invivotherapeutics.com. A copy of our Code of Business Conduct and Ethics can also be obtained free of charge by contacting our Secretary, c/o InVivo Therapeutics Holdings Corp., One Kendall Square, Suite B14402, Cambridge, MA 02139. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics by posting such information on our website.

Compensation Committee Interlocks and Insider Participation

None of the members of the Compensation Committee was at any time during 2017 or at any other time an officer or employee of our company. None of our executive officers serves as a member of the board of directors or compensation committee of any other entity that has one or more executive officers serving as a member of our Board or the Compensation Committee.

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COMPENSATION DISCUSSION AND ANALYSIS

Executive Summary

This Compensation Discussion and Analysis explains our compensation philosophy, objectives, policies, and practices with respect to our Chief Executive Officer and our other named executive officers. For 2017, our named executive officers are:

- Richard Toselli, our Acting Chief Executive Officer;
- Christopher McNulty, our Chief Financial Officer;
- Pamela Stahl, our Chief Commercial Officer;
- Tamara Joseph, our SVP, General Counsel and Chief Compliance Officer;
- Mark D. Perrin, our former Chief Executive Officer and former Chairman of the Board; who resigned from the Company effective December 18, 2017;
- Thomas Ulich, M.D., our former Chief Scientific Officer; whose position with the Company was eliminated on August 28, 2017 as part of a strategic corporate restructuring; and
- Melanie Morel-Ferris, our former interim Chief Financial Officer; who served in this capacity from January 2, 2017 through March 28, 2017 and who resigned from the Company effective October 27, 2017.

Compensation Philosophy and Objectives

The primary objectives of our executive compensation program are to attract, motivate, retain and reward high-quality executives, to compensate our executives with a pay-for-performance philosophy that rewards executives for meeting performance-based goals, and to align the interests of our executives with our stockholders by having equity-based compensation as an important portion of our executives total compensation.

As part of our overall compensation philosophy, we target the 25th percentile of our peer group companies for target cash compensation to our executive officers, and the median of our peer group companies for their total direct compensation (cash plus equity-based compensation). Our annual bonus program is based on the achievement of certain corporate performance goals and, in the case of our named executive officers other than our Chief Executive Officer, individual performance goals. This approach enables us to deploy more of our cash resources to advancing our clinical development programs while providing executives with strong equity opportunities, further linking their interests with those of our stockholders. In addition to aligning our compensation practices for our named executive officers with comparable companies in our industry, we also seek to have an executive compensation structure that is fair relative to other professionals within our company. Our objective is to foster a performance-oriented culture, where individual performance is aligned with business objectives and the creation of long-term stockholder value.

Role of the Compensation Committee

The Compensation Committee approves or recommends to the Board for approval the compensation of our Chief Executive Officer and all other executive officers, administers our incentive compensation and stock plans and oversees our employee benefit plans. Our Compensation Committee is appointed by the Board and consists entirely of directors who are independent under the NASDAQ Listing Rules, outside directors for purposes of Section 162(m) of the Internal Revenue Code and non-employee directors for purposes of Rule 16b-3 under the Exchange Act. Our Compensation Committee is currently composed of Messrs. DiPietro and Hatfield and Drs. Marshak and Roberts.

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Compensation-Setting Process

The Compensation Committee reviews and recommends to our Board the compensation of our Chief Executive Officer, and reviews and approves, with input from management, the compensation of our other executive officers, including our named executive officers. This review is based on an evaluation of each officer s performance, corporate goals and objectives, and such other information as the Compensation Committee may request, including surveys of executive compensation practices at comparable companies.

Role of our Management

Our Chief Executive Officer and our human resources and finance departments work together to develop and prepare materials requested by and to be presented to the Compensation Committee, including analyses of financial data, peer data comparisons, and other briefing materials. Our Chief Executive Officer and our Vice President, Human Resources present the compensation proposals for our named executive officers (other than our Chief Executive Officer), along with any background information, to the Compensation Committee for review and consideration. The Compensation Committee may approve, modify, or reject those proposals, or may request additional information from management on those matters. Our Chief Executive Officer does not attend any portion of meetings at which his compensation is determined.

Role of Independent Compensation Consultant

Pursuant to its charter, the Compensation Committee has the authority to select and retain independent compensation consultants or advisors, at our expense, to assist it in carrying out its duties and responsibilities. In 2017 the Compensation Committee engaged Pearl Meyer to perform duties requested by the committee including:

- providing recommendations on the composition of the Peer Group described under Competitive Market Assessment below;
- analyzing executive compensation in comparison to market benchmarks;
- updating the Compensation Committee on executive compensation market trends; and
- advising the Committee on the 2017 short-term and long-term incentive designs.

The consultant spoke with the chair of the Compensation Committee, as well as with management, in preparing for committee meetings, regularly attended committee meetings and met from time to time in executive session with the Compensation Committee without the presence of management.

Competitive Market Assessment

On an annual basis, the Compensation Committee reviews, with its compensation consultant, relevant market benchmarks for the Company s executive compensation. The Compensation Committee uses this information to ensure that it is acting on an informed basis and to establish points of reference to determine whether and to what extent it is establishing competitive levels of compensation for our named executive officers.

For 2017 compensation decisions, the Compensation Committee considered compensation information of peer group public companies in the biotechnology and pharmaceutical industries. The criteria for selection of the companies in the peer group included the size of a company, its business development stage, and how recently a company had become publicly owned. All companies in the peer group have less than 300 employees and a primary industry focus of pharmaceutical products, diagnostic substances, or therapeutic preparations, with most peers having products in the preclinical to phase II product development stages. Companies were selected with various revenue sizes because we are recruiting from and competing for executive talent with companies that are generating revenue. For 2017, the peer group companies consisted of:

Acceleron Pharma, Inc.	Epizyme, Inc.

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Agenus Inc.	Flexion Therapeutics, Inc.
Akebia Therapeutics, Inc.	Genocea Biosciences, Inc.
AxoGen Inc.	Idera Pharmaceuticals, Inc.
Cerulean Pharma Inc.	Organovo Holdings Inc.
Curis, Inc.	OvaScience, Inc.
Dicerna Pharmaceuticals, Inc.	Sarepta Therapeutics, Inc..
Dimension Therapeutics Inc.	Verastem, Inc..
Eleven Biotherapeutics, Inc.	ZIOPHARM Oncology, Inc.
Enanta Pharmaceuticals, Inc.	

The Compensation Committee also considered market data compiled by Pearl Meyer from industry-relevant published compensation survey data, employing the appropriate headcount and executive role perspectives, as an additional market check.

Say-on-Pay Advisory Vote

Our most recent shareholder advisory vote on executive compensation was held at our 2016 annual meeting of stockholders. At our 2016 annual meeting, approximately 84% of the votes cast approved the compensation of our named executive officers as disclosed in the proxy statement delivered to our stockholders in connection with the 2016 annual meeting. We understood this to mean that stockholders generally approved of our compensation policies and determinations in 2016. However, the Compensation Committee still undertook a review of our compensation policies and determinations following the 2016 annual meeting. After this review and in consideration of evolving best practices in executive compensation by comparable public companies in our industry, upon the recommendation of the Compensation Committee, we determined not to make any significant changes to our executive compensation decisions and policies.

Elements of Executive Compensation Program

Generally, our executive compensation program consists of five components: base salary, annual bonus incentives, long-term equity incentives, benefits, and severance or termination protection.

Base Salary. Base salary is the primary fixed component of our executive compensation program. The Compensation Committee believes that a competitive base salary is necessary to attract and subsequently retain a management team with the requisite skills to lead our company. The Compensation Committee typically reviews salaries for potential adjustments in January of each fiscal year and may make adjustments at other times as needed. Generally, our Compensation Committee believes that adjustments to base salary should reflect the responsibilities of the executive, the executive s performance for the preceding year, demand in the market for the particular executive position, and the pay of the other members of the executive team, as well as targeting our cash compensation at the 25th percentile of our peer group companies. Base salaries for our named executive officers are further described below.

Annual Incentive Bonus Plan. Our annual incentive bonus plan provides performance-based incentives that motivate and

reward achievement of corporate and individual performance goals. Under the annual incentive bonus plan, goals are set at the beginning of each year that are appropriate in light of our business plans and take into consideration our financial, operational and strategic priorities. Currently, payouts under our annual incentive bonus plan to our Chief Executive Officer are based on the achievement of corporate objectives, and for other named executive officers, payouts are based on a combination of corporate objectives and individual performance goals. Corporate objectives are recommended by the Committee, with input from management and an independent eternal compensation consultant, and discussed with and approved by the Board. Individual performance goals for our named executive officers, other than our Chief Executive Officer, are determined by the Compensation Committee with input from our Chief Executive Officer and are intended to measure our executive officers achievement of specific projects. At the end of each year, the Compensation Committee determines the degree to which individual performance goals have been met. The Board determines the degree to which corporate performance objectives have been met and the associated payouts to each named executive officer. The Compensation Committee may grant

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bonuses that are above, at, or below the individual target bonus for named executive officers, except the Chief Executive Officer, based on the level of achievement if it determines that such bonuses are warranted and are in the best interests of our company and our stockholders. The Board may grant the Chief Executive Officer a bonus that is above, at, or below the target bonus based on the level of achievement of corporate objectives if it determines that such bonus is warranted and is in the best interests of the Company and our stockholders. Goals, results and approved payouts under our annual incentive plan for 2017 are further described below.

Long-Term Equity Incentives. Consistent with the practices of peer group companies, we provide equity incentive compensation to our named executive officers. These awards aim to align the interests of our executive officers with those of our stockholders to create long-term stockholder value, as well as motivate and retain talented executives.

Our named executive officers are eligible to receive annual equity awards, although an annual award is not guaranteed. Individual equity award determinations for named executive officers, except the Chief Executive Officer, are made by the Compensation Committee with respect to the frequency and size of the equity award to be granted to the named executive officers. The determination for equity awards for the Chief Executive Officer is recommended by the Compensation Committee to the Board and approved by the Board, with respect to the frequency and size of the equity award to be granted to the Chief Executive Officer. In making these determinations, the Compensation Committee considers performance relative to the strategic and financial objectives of our company and the individual performance of each named executive officer. Our equity awards generally vest over a four-year period, with 25% vesting on the first anniversary of the date of grant and thereafter on a monthly basis in 36 equal installments. At the time of hire, we typically provide our named executive officers with an equity incentive award in the form of stock options although we have also granted restricted stock units, or RSUs, in connection with hire.

We currently grant stock options and restricted stock units and not other forms of equity to our executive officers because we believe stock options and restricted stock units are consistent with the risk profile of a pre-commercial company. We review our program annually to determine the appropriate form and terms of awards given the business strategy.

Benefits and Perquisites. We provide the following benefits to our named executive officers generally on the same basis as the benefits provided to all employees: medical, dental and vision insurance, including a flexible spending account option, life insurance, short and long-term disability, and certain commuting expenses. We also match, in the form of shares of our common stock, contributions to our 401(k) profit sharing plan, in amounts up to 5% of each named executive officer s annual compensation. Our matching contributions become 100% vested after the employee has been employed by us for four years. In addition, in 2015 we adopted, and our stockholders approved, an employee stock purchase plan to allow our employees to purchase shares of our common stock at a discount using after-tax payroll deductions. We may also provide additional benefits or perquisites under contractual agreements to our named executive officers, including housing allowances and commuting expenses.

Severance/Termination Benefits. Under contractual agreements with our named executive officers, we have agreed to provide severance payments in connection with the termination of the executive, including in connection with a change in control. These arrangements are described in the Executive Compensation section under Potential Payments upon Termination or Change in Control.

Compensation Decisions for 2017

Base Salaries. The initial base salaries of our named executive officers were determined upon each officer s hire based on such officer s industry experience, expertise, and demand within our industry, and may be adjusted from time to time following hiring. Please see the Summary Compensation Table below for the actual amounts paid to our named executive officers in 2017.

Named Executive Officer	2016 Salary ($)(1)	Increase %	2017 Salary ($)(2)
Richard Toselli(3)	n/a	n/a	435,000
Mark Perrin(4)	445,050	16.6%	519,000
Christopher McNulty(5)	276,863	11.6%	309,000
Melanie Morel-Ferris(6)	155,000	16.1%	180,000
Pamela J Stahl	335,000	0.0%	335,000
Tamara Joseph	256,680	3.4%	265,491
Thomas Ulich	336,375	3.8%	349,000

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(1) Annual salaries as of January 1, 2016, including any annual increase, for incumbent executive officers, and as of the start date for new executive officers hired mid-year.

(2) Annual salaries as of January 1, 2017, including any annual increase, for incumbent executive officers, and as of the start date for new executive officers hired mid-year.

(3) Dr. Toselli joined our company as Acting Chief Executive Officer effective December 18, 2017.

(4) Mr. Perrin resigned from our company effective December 18, 2017. Mr. Perrin s annual salary increase contemplated the elimination of certain allowances relating to relocation.

(5) In addition to an annual increase, Mr. McNulty s salary increased from $309,000 to $335,000 on March 28, 2017, following his promotion to Chief Financial Officer and Mr. McNulty s salary increased from $276,863 to $300,000 on June 13, 2016 in connection with expanded responsibilities.

(6) In addition to an annual increase, Ms. Morel-Ferris salary increased in connection with her assumption of the acting Chief Financial Officer duties on January 2017.

Annual Incentive Bonuses. All of our named executive officers were eligible to participate in our 2017 incentive bonus plan, which consisted of corporate objectives and, for our named executive officers other than our Chief Executive Officer, individual objectives. For each of our executive officers, the Compensation Committee sets a target bonus amount expressed as a percentage of base salary. For 2017, the target bonus amount was set at 50% of base salary for our Chief Executive Officer and 35% of base salary for our other named executive officers.

For our named executive officers other than our Chief Executive Officer, the 2017 incentive bonus was weighted 75% to achievement of corporate objectives and 25% to achievement of individual objectives. For Mr. Perrin, our former Chief Executive Officer, the 2017 bonus was weighted 100% to achievement of corporate objectives. Dr. Toselli did not participate in the 2017 incentive bonus plan because he was serving as a consulting Chief Medical Officer from July 2017 to December 2017, when he assumed the role of Acting Chief Executive Officer.

The corporate objectives were set with a reasonable level of difficulty that required our named executive officers to perform at a high level to meet the objectives, and the likelihood of attaining the objectives was not assured. The Board has full discretion with respect to the amount and payment of bonuses, including adjustments to the objectives, weightings and actual amounts, and payout terms of the annual bonuses. This discretion is communicated to the executives. In January 2018, the Board, following the recommendation of the Compensation Committee, determined that no bonuses would be awarded for 2017 for named executive officers regardless of whether any bonus objectives were met, including corporate objectives or individual objectives.

The 2017 corporate objectives and weightings recommended by the Compensation Committee and approved by the Board in 2017, and the actual weightings achieved as determined by the Board for 2017 performance, were as follows:

Objective		Target Weighting	Level of Attainment(1)
1.	20 evaluable patients implanted with *Neuro-Spinal Scaffold* implant in probable benefit pivotal thoracic SCI clinical study	35%	0%
2.	Initiate ex-US cervical SCI study by the end of Q-2	15%	15%
3.	Evaluate localized delivery strategies that improve the efficacy or safety of therapeutic agents, and recommend and execute two business transactions that the advancement of one or more therapeutic products (i.e., a cell, protein, or gene therapy) to an initial FDA meeting.(2)	25%	0%
4.	Maintain sufficient financial resources to support company operations	25%	0%
	Total	100%	15%

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(1) Although the level of attainment for the objectives was 15%, in January 2018 the Board, following the recommendation of the Compensation Committee, determined that no bonuses would be awarded for 2017 for named executive officers.

(2) Examples of strategic transactions include a licensing of technology or intellectual property, a business deal to acquire or codevelop a therapeutic product such as a cell, protein, or gene therapy; a letter of commitment/intent from another institution with a synergistic asset, a manufacturing or supply partnership or agreement, or an out-license of our spinal cord delivery intellectual property.

Long-Term Equity Incentive Awards. We use equity awards to reward long-term value creation and as a retention tool. The size of the equity awards approved by our Compensation Committee for each named executive officer reflects individual contributions to company performance and competitive positioning relative to the market. In 2016, we opted to shift the timing of our annual equity awards from December to January. The long-term equity awards granted in January 2017 to our named executive officers were comprised of stock option awards.

Annual equity awards were made in January 2017, based on company and individual performance in 2016, expected future individual performance, retention considerations, and market data provided by our compensation consultant. In January 2017, the Compensation Committee awarded stock options to our named executive officers, other than our Chief Executive Officer, and the Board awarded stock options to our Chief Executive Officer, as follows:

Named Executive Officer	Stock Options (#)
Rich Toselli	n/a
Mark Perrin	320,000
Christopher McNulty	75,000
Melanie Morel-Ferris	25,000
Pamela J. Stahl(1)	35,000
Tamara Joseph	120,000
Thomas Ulich	150,000

(1) The number of options granted was pro-rated based on Ms. Stahl s appointment as Chief Commercial Officer on September 14, 2016.

In January 2018, the Board, following the recommendation of the Compensation Committee, determined that no annual equity awards would be granted to named executive officers based on performance in 2017.

In March 2017, the Compensation Committee granted Mr. McNulty a stock option award to purchase 29,297 shares of common stock in connection with his appointment as Chief Financial Officer, as further described below. The award to Mr. McNulty vests over a four-year period, with 25% vesting on the first anniversary of the grant date and the remainder vesting monthly in 36 equal installments until fully vested

on the fourth anniversary of the grant date, provided that Mr. McNulty remains continually employed by the Company on each such vesting date.

In September 2017, the Compensation Committee approved a grant to Ms. Morel-Ferris of a restricted stock unit award for 60,000 shares under the Company s 2015 Equity Incentive Plan and a Restricted Stock Unit Agreement in connection with an employee retention program. The award to Ms. Morel-Ferris vested over a two-year period, with 50% vesting on the first anniversary of the grant date and 50% vesting on the second anniversary of the grant date, provided that Ms. Morel-Ferris remained continually employed by the Company on each such vesting date. Ms. Morel-Ferris resigned from the Company effective October 27, 2017.

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In December 2017, the Compensation Committee recommended and the Board approved a grant to Dr. Toselli of a restricted stock unit award for 300,000 shares under the Company s 2015 Equity Incentive Plan and a Restricted Stock Unit Agreement in connection with his appointment as Acting Chief Executive Officer, as further described below. The award to Dr. Toselli vests over a four-year period, with 25% vesting on the first anniversary of the grant date and the remainder vesting monthly in 36 equal installments until fully vested on the fourth anniversary of the grant date, provided that Dr. Toselli remains continually employed by the Company on each such vesting date.

Compensation Practices and Risk

The Compensation Committee has reviewed our compensation policies as generally applicable to our employees and believes that our policies do not encourage excessive and unnecessary risk-taking, and that the level of risk that they do encourage is not reasonably likely to have a material adverse effect on the Company. In making this determination, the Compensation Committee considered the following:

- Our salaries, annual bonuses and annual equity grants are largely determined based on comparisons with peer companies, and annual incentive bonuses are based on financial and/or operational performance goals and business criteria such as capital raising, regulatory filings/approvals, progress in pre-clinical and clinical trials, intellectual property filings or issuances, and business development transactions, and individual performance objectives, set by the Committee.

- The Committee has discretion to modify amounts awarded under our programs, and our system of internal control over financial reporting and code of business conduct and ethics reduce the likelihood of manipulation of our financial performance to enhance payments under any of our incentive plans.

- There is balance between short-term (bonus measures) and long-term (stock options or RSUs with service-based vesting) performance focus.

- Our severance benefits neither insulate management from risky business strategies nor provide an enticement to pursue risky strategies.

Arrangements with Named Executive Officers

Richard Toselli, Acting Chief Executive Officer. Under our employment agreement with Dr. Toselli, Dr. Toselli receives an annual base salary, subject to adjustment from time to time, and is eligible to receive an annual cash bonus equal to 50% of his annual salary, subject to his performance of specified objectives to be established by the Board (or a

designated Board committee) each year. Dr. Toselli is eligible to receive all medical, dental and other benefits to the same extent as provided to other senior management employees. Dr. Toselli is eligible to receive a one-time sign-on bonus in the amount of $100,000 provided that he remains an active employee on January 31, 2018, to be paid February 1, 2018. Additionally, Dr. Toselli is eligible for a one-time bonus of $150,000, upon the approval by the U.S. Food and Drug Administration of the Company s proposed plans with respect to one or more clinical trials. Provided that Dr. Toselli is still employed by the Company on February 1, 2018 and has agreed to become the Company s Chief Executive Officer rather than Acting Chief Executive Officer, Dr. Toselli will become eligible for certain severance benefits under his employment agreement.

Mark Perrin, Former Chief Executive Officer. Under our employment agreement with Mr. Perrin, Mr. Perrin received an annual base salary, subject to adjustment from time to time, and was eligible to receive an annual cash bonus equal to 50% of his annual salary, subject to his performance of specified objectives to be established by the Board (or a designated Board committee) each year. Mr. Perrin was eligible to receive all medical, dental and other benefits to the same extent as provided to other senior management employees. In connection with his relocation to the Boston area, we agreed to arrange up to 12 months of corporate housing for Mr. Perrin, and we extended this corporate housing benefit through January 2017, such amount to be subject to a tax gross-up. Mr. Perrin was eligible for certain severance benefits under his employment agreement.

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Consistent with the severance terms provided to Mr. Perrin pursuant to his employment agreement, the Company agreed, pursuant to the terms of a separation agreement effective December 18, 2017 to pay severance (consisting of base salary in effect at the time of termination) to Mr. Perrin upon his termination for a period of 18 months, plus health insurance benefits for a period of 6 months. In addition, the Company accelerated the vesting of the unvested portion of any options held by Mr. Perrin to the extent of 12 additional months upon his termination date. The severance payments are in addition to any accrued obligations to Mr. Perrin unpaid by the Company prior to the date of termination. Mr. Perrin s separation agreement includes a general release of claims.

Thomas Ulich, Former Chief Scientific Officer. Under the employment agreement with Dr. Ulich, Dr. Ulich received an annual base salary, subject to adjustment from time to time, and was eligible to receive benefits to the same extent as provided to our other senior management employees, including medical and dental benefits. We agreed to reimburse Dr. Ulich for commuting expenses related to travel between his home in New York and our headquarters. In addition, Dr. Ulich was eligible to receive an annual target bonus equal to 35% of his annual salary, subject to his performance of specified objectives to be established by our Chief Executive Officer each year. Consistent with the severance terms provided to Dr. Ulich pursuant to his employment agreement, the Company agreed, in connection with his separation, to pay severance (consisting of base salary in effect at the time of termination) to Dr. Ulich upon his termination for a period of 12 months, plus health insurance benefits for a period of 6 months. The severance payments are in addition to any accrued obligations to Dr. Ulich unpaid by the Company prior to the date of termination. Dr. Ulich signed a general release of claims in connection with his separation.

Christopher McNulty, Chief Financial Officer. We entered into an employment agreement with Mr. McNulty in March 2017. Under the terms of his agreement, Mr. McNulty receives an annual base salary, subject to adjustment from time to time, and is eligible to receive an annual cash bonus equal to 35% of his annual salary, subject to his performance of specified objectives to be established by the Board (or a designated Board committee) each year. Mr. McNulty is eligible to receive all medical, dental and other benefits to the same extent as provided to other senior management employees. Mr. McNulty is eligible for certain severance benefits as described in more detail under the heading Potential Payments Upon Termination or Change in Control.

Tamara Joseph, SVP, General Counsel & Chief Compliance Officer. We entered into an employment agreement with Ms. Joseph in August 2015, which replaced the terms of an offer letter dated March 14, 2014, which previously governed the terms of Ms. Joseph s employment with the Company. Under the terms of her agreement, Ms. Joseph receives an annual base salary, subject to adjustment from time to time, and is eligible to receive an annual cash bonus equal to 35% of her annual salary, subject to her performance of specified objectives to be established by the Board (or a designated Board committee) each year. Ms. Joseph is eligible to receive all medical, dental and other benefits to the same extent as provided to other senior management employees. Ms. Joseph is eligible for certain severance benefits as described in more detail under the heading Potential Payments Upon Termination or Change in Control.

Pursuant to a letter agreement dated January 19, 2018, Ms. Joseph s employment will terminate effective February 7, 2017 and Ms. Joseph will be entitled to the severance benefits provided under her employment agreement. In addition, Ms. Joseph has agreed to provide consulting services to the Company for six months following the termination of her employment pursuant to the terms of a consulting agreement made and entered into as of January 19, 2018 and commencing on February 9, 2018. Under the consulting agreement, Ms. Joseph will be paid an hourly rate of $400.

Pamela J. Stahl, Chief Commercial Officer. We entered into an employment agreement with Ms. Stahl in August 2016. Under the terms of her agreement, Ms. Stahl receives an initial annual base salary, subject to adjustment from time to time, and is eligible to receive benefits to the same extent as provided to our other senior management employees, including medical and dental benefits. In addition, under the agreement, Ms. Stahl is eligible to receive an annual target bonus equal to 35% of her annual salary, subject to her performance of specified objectives to be established by our Chief Executive Officer each year. Ms. Stahl is currently eligible for certain severance benefits under her employment agreement as described in more detail under the heading Potential Payments Upon Termination or Change in Control.

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EXECUTIVE COMPENSATION

Set forth below is information regarding the compensation of (i) all persons serving as our Chief Executive Officer or Chief Financial Officer at any time during 2017 and (ii) our other most highly compensated executive officers at the end of 2017. Such officers are collectively referred to as our named executive officers.

Summary Compensation Table

The following table sets forth information regarding the compensation awarded to, earned by, or paid to the named executive officers.

Name and Principal Position	Year	Salary ($)	Bonus ($)