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