INVIVO THERAPEUTICS HOLDINGS CORP.
Form S-1/A
February 09, 2018
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As filed with the Securities and Exchange Commission on February 9, 2018

Registration No. 333-222738

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON D.C. 20549

Amendment No. 1

to

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

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 FEBRUARY 9, 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 February 8, 2018, the last reported sale price of our common stock on The Nasdaq Global Market was $0.53 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. Three 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 or 24-month visits. Two of the 16 patients were initially assessed to have improved from complete AIS A SCI to incomplete AIS B SCI, but each was later assessed to have reverted to complete AIS A SCI prior to the six-month examination. One of these two 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.

Recent Developments

On February 2, 2018, our Board of Directors appointed Dr. Richard Toselli, M.D. as President and Chief Executive Officer, effective immediately. Following the recommendation of our Governance and Nominating Committee, the Board also elected Dr. Toselli to serve on the Board as a director, effective immediately. Dr. Toselli has been designated as a Class III director to serve in accordance with our By-Laws until our 2020 Annual Meeting of Stockholders and until his successor has been duly elected and qualified, or until his earlier death, resignation, retirement, removal. or disqualification. For more more information about Dr. Toselli, including his background and prior service with the Company, refer to the Management section of this Prospectus.

The terms of Dr. Toselli s employment are governed by the employment agreement Dr. Toselli entered into in connection with his appointment as Acting Chief Executive Officer on December 18, 2017, described in the Compensation Discussion and Analysis section of this prospectus. Also in connection with his previous appointment as Acting Chief Executive Officer, Dr. Toselli entered into our standard form of indemnification agreement.

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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 an 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 are currently exercisable for 13,353 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 37,389 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;
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