INVIVO THERAPEUTICS HOLDINGS CORP.
Form 424B4
June 22, 2018
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Filed Pursuant to Rule 424(b)(4)
Registration Nos. 333-224424 and 333-225768

Prospectus

InVivo Therapeutics Holdings Corp.

388,403 Shares of Common Stock and
388,403 Warrants to Purchase Shares of Common Stock

and

6,242,811 Pre-Funded Warrants to Purchase Shares of Common Stock and

6,242,811 Warrants to Purchase Shares of Common Stock

We are offering 388,403 shares of common stock, together with warrants (the Series A warrants) to purchase 388,403 shares of common stock at a combined public offering price of $2.00 per share and Series A warrant (and the shares issuable from time to time upon exercise of the Series A warrants) pursuant to this prospectus. The shares of common stock and Series A warrants will be separately issued, but the shares of common stock and Series A warrants will be issued and sold to purchasers in the ratio of one to one. Each Series A warrant will have an exercise price of 2.00 per share, will be exercisable upon issuance and will expire five years from the date of issuance. The Series A warrants will be issued in book-entry form pursuant to a warrant agency agreement between us and Continental Stock Transfer and Trust Company, as warrant agent, respectively.

We are also offering 6,242,811 pre-funded warrants (the Series B pre-funded warrants and collectively with the Series A warrants, the warrants) to those purchasers, whose purchase of shares of common stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering in lieu of the shares of our common stock that would result in ownership in excess of 4.99% (or, at

the election of the purchaser, 9.99%). Each Series B pre-funded warrant will be exercisable for one share of common stock. Each Series B pre-funded warrant is being sold together with the same Series A warrants described above being sold with each share of common stock. The combined public offering price for each such Series B pre-funded warrant, together with the Series A warrant, is $1.99, the per share public offering price for the common stock in this offering less the $0.01 per share exercise price of each such Series B pre-funded warrant. Each Series B pre-funded warrant will be exercisable upon issuance and will expire twenty years from the date of issuance. The Series B pre-funded warrants and Series A warrants are immediately separable and will be issued separately in this offering. The Series B warrants will be issued in book-entry form pursuant to a warrant agency agreement between us and Continental Stock Transfer and Trust Company, as warrant agent, respectively.

Our common stock is listed on the Nasdaq Capital Market under the symbol NVIV. On June 20, 2018, the last reported sale price of our common stock on the Nasdaq Capital Market was $3.37 per share.

Investing in the offered securities involves a high degree of risk. See Risk Factors beginning on page 10 of this prospectus for a discussion of information that you should consider before investing in our securities.

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.

	Per Share and Series A Warrant	Per Series B Pre-Funded Warrant and Series A Warrant	Total
Public offering price	$ 2.00	$ 1.99	$ 13,200,000
Underwriting discount (1)	$ 0.16	$ 0.16	$ 1,056,000
Proceeds, before expenses, to us	$ 1.84	$ 1.83	$ 12,144,000

(1) We refer you to Underwriting on page 50 for additional information regarding underwriting compensation.

We have granted a 45-day option to the underwriter to purchase up to an additional 989,997 shares of common stock and/or 989,997 Series A warrants from us solely to cover over-allotments, if any. The shares and/or Series A warrants issuable upon exercise of the underwriter option are identical to those offered by this prospectus and have been registered under the registration statement of which this prospectus forms a part. If the underwriter exercises the option in full, the total discount and commission will be $1,214,400 and the total net proceeds, before expenses, to us will be $13,556,801.

The underwriter expects to deliver the shares and warrants to purchasers in the offering on or about June 25, 2018.

LADENBURG THALMANN

Prospectus dated June 20, 2018

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ABOUT THIS PROSPECTUS

The registration statement we filed with the Securities and Exchange Commission (the SEC) includes exhibits that provide more detail of the matters discussed in this prospectus. You should read this prospectus, the related exhibits filed with the SEC, and the documents incorporated by reference herein before making your investment decision. You should rely only on the information provided in this prospectus and the documents incorporated by reference herein or any amendment thereto. In addition, this prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the heading Where You Can Find Additional Information.

We have not, and the underwriter has not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus, the documents incorporated by reference herein or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. The information contained in this prospectus, the documents incorporated by reference herein or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

This prospectus is an offer to sell only the securities offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. We are not, and the underwriter is not, making an offer to sell these securities in any state or jurisdiction where the offer or sale is not permitted.

All other trademarks, trade names and service marks appearing in this prospectus or the documents incorporated by reference herein are the property of their respective owners. Use or display by us of other parties trademarks, trade dress or products is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owner. Solely for convenience, trademarks, tradenames and service marks referred to in this prospectus appear without the ® and symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and trade names.

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PROSPECTUS SUMMARY

This summary provides an overview of selected information contained elsewhere or incorporated by reference in this prospectus and does not contain all of the information you should consider before investing in our securities. You should carefully read the prospectus, the information incorporated by reference and the registration statement of which this prospectus is a part in their entirety before investing in our securities, including the information discussed under Risk Factors in this prospectus and the documents incorporated by reference and our financial statements and notes thereto that are incorporated by reference in this prospectus. Some of the statements in this prospectus and the documents incorporated by reference herein constitute forward-looking statements that involve risks and uncertainties. See information set forth under the section Special Note Regarding Forward-Looking Statements. 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.

Business Overview

Overview

We are a research and clinical-stage biomaterials and biotechnology company with a focus on treatment of spinal cord injuries, or SCIs. Our approach to treating acute SCIs is based on our investigational *Neuro-Spinal Scaffold* implant, a bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord and is intended to treat acute SCI. The *Neuro-Spinal Scaffold* implant incorporates intellectual property licensed under an exclusive, worldwide license from Boston Children s Hospital and the Massachusetts Institute of Technology. We also plan to evaluate other technologies and therapeutics that may be complementary to our development of the *Neuro-Spinal Scaffold* implant or offer the potential to bring us closer to our goal of redefining the life of the SCI patient.

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

Our Clinical Program

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

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.

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The INSPIRE Study

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

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The purpose of The INSPIRE Study, which was the original study, was to evaluate whether the *Neuro-Spinal Scaffold* implant is safe and demonstrates probable benefit for the treatment of complete T2-T12 neurological level of injury (NLI) SCI. The primary endpoint was defined as the proportion of patients achieving an improvement of at least one AIS grade at six months post-implantation. Additional endpoints included measurements of pain, sensory and motor scores, bladder and bowel function, Spinal Cord Independence Measure (a disability scale for patients with SCI), and quality of life. The INSPIRE Study included an Objective Performance Criterion, or OPC, which is a measure of study success used in clinical studies designed to demonstrate safety and probable benefit in support of an HDE approval. At the time enrollment of patients in The INSPIRE Study was placed on hold, the OPC was defined as 25% or more of the patients in the study demonstrating an improvement of at least one AIS grade at the six month post-implantation visit.

The FDA approved the enrollment of up to 30 patients in The INSPIRE Study so that there would be at least 20 evaluable patients at the primary endpoint analysis, accounting for events such as screen failures or deaths that would prevent a patient from reaching the primary endpoint visit. Of the 19 patients implanted in The INSPIRE Study, 16 patients have reached the six-month primary endpoint visit. Of these 16, seven had improved from complete AIS A SCI to incomplete SCI (two patients to AIS C and five patients to AIS B) at the six-month primary endpoint visit and nine had not demonstrated improvement at that visit. Three of the seven patients who improved were assessed to have AIS B SCI at the six-month primary endpoint and were later assessed to have improved to AIS C SCI at the 12 or 24-month visits. Two of the 16 patients were initially assessed to have improved from complete AIS A SCI to incomplete AIS B SCI, but each was later assessed to have reverted to complete AIS A SCI prior to the six-month examination. One of these two was then assessed at the six-month visit to have improved again to AIS B and the other remained AIS A. Since we have closed enrollment, the target of enrolling 20 evaluable patients into The INSPIRE Study will not be reached.

The FDA had previously recommended that we include a randomized, concurrent control arm in The INSPIRE Study. Acting on the FDA s recommendation, we proposed and received approval for the INSPIRE 2.0 Study (described below) to supplement the existing clinical evidence for the *Neuro-Spinal Scaffold* implant. In addition, as one source of comparator data, we initiated the Contemporary Thoracic SCI Registry Study, or the CONTEMPO Registry Study. The CONTEMPO Registry Study utilizes existing databases and registries to develop a historical comparator that, to the extent possible, matches patients to those patients enrolled in The INSPIRE Study. The CONTEMPO Registry Study is designed to provide comprehensive natural history benchmarks for The INSPIRE Study results that include SCI patients with similar baseline characteristics treated since 2006. The CONTEMPO Registry Study includes data from the Christopher & Dana Reeve Foundation North American Clinical Trials Network Registry (NACTN), as well as the Model Systems Registry and the European Multicenter Study about Spinal Cord Injury (EMSCI). We have submitted a protocol for the CONTEMPO Registry Study to the FDA and we announced top-line findings from CONTEMPO in March 2018 from a total of 170 patients from the three registries: 12 individuals from NACTN, 64 from EMSCI, and 94 from Model Systems. AIS conversion rates at approximately six months post-injury varied from 16.7% 23.4% across the three registries. In two of the registries, there was a skew of the patient population to low (T10-T12) thoracic injuries, representing 46-47% of the registry population. This compares to just four out of sixteen patients (25%) in follow-up in the INSPIRE study with low thoracic injuries. Patients with low thoracic injuries are known to have the best prognoses, and the conversion rates were the highest in the low thoracic group in all three registries and the INSPIRE study. When all three registries were normalized to the INSPIRE patient population distribution across T2-T5, T6-T9 and T10-T12 injury groups, the normalized conversion rate for CONTEMPO registries ranged from 15.5%-20.6%. We cannot be certain what additional information or studies will be required by the FDA to approve our HDE submission.

INSPIRE 2.0 Study

Our *Neuro-Spinal Scaffold* implant has been approved to be studied under our approved IDE in the INPSIRE 2.0 Study, which is titled the Randomized, Controlled, Single-blind Study of Probable Benefit of the *Neuro-Spinal Scaffold* for Safety and Neurologic Recovery in Subjects with Complete Thoracic AIS A Spinal Cord Injury as Compared to Standard of Care. The purpose of the INSPIRE 2.0 Study is to assess the overall safety and probable benefit of the *Neuro-Spinal Scaffold* for the treatment of neurologically complete thoracic traumatic acute SCI. The INSPIRE 2.0 Study is designed enroll 10 subjects into each study arm, which we refer to as the Scaffold Arm and the Comparator Arm. Patients

in the Comparator Arm will receive standard of care, which

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is spinal stabilization without dural opening or myelotomy. The INSPIRE 2.0 Study is a single blind study, meaning that the patients and assessors are blinded to treatment assignments. The FDA approved the enrollment of up to 35 patients in this study so that there would be at least 20 evaluable patients (10 in each study arm) at the primary endpoint analysis, accounting for events such as screen failures or deaths that would prevent a patient from reaching the primary endpoint visit. We may conduct the INSPIRE 2.0 Study at up to 26 sites in the United States. Enrolling patients in the INSPIRE 2.0 Study will also require the approval of the IRBs at each clinical site. We estimate that from study initiation, enrollment will take an approximately 18 months, and the total time to completion of the INSPIRE 2.0 study is estimated to be two years from study initiation.

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

We received approval for the INSPIRE 2.0 Study in early March 2018. We believe this sets us in a direction towards a path to approval under the HDE regulatory program, and we are focused on exploring financing mechanisms to support the INSPIRE 2.0 Study.

Although The INSPIRE Study is structured with the OPC as the primary component for demonstrating probable benefit, the OPC is not the only variable that the FDA would evaluate when reviewing a future HDE application. Similarly, while our planned INSPIRE 2.0 Study is structured with a definition of study success requiring a minimum difference between study arms in the proportion of subjects achieving improvement, that success definition is not the only factor that the FDA would evaluate in the future HDE application. Approval is not guaranteed if the OPC is met for The INSPIRE Study or the definition of study success is met for the INSPIRE 2.0 Study, and even if the OPC or definition of study success are not met, the FDA may approve a medical device if probable benefit is supported by a comprehensive review of all clinical endpoints and preclinical results, as demonstrated by the sponsor s body of evidence.

In 2016, the FDA accepted our proposed HDE modular shell submission and review process for the *Neuro-Spinal Scaffold* implant. The HDE modular shell is comprised of three modules: a preclinical studies module, a manufacturing module, and a clinical data module. As part of its review process, the FDA reviews 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 that may trigger the review clock for an approval decision. We submitted the first module in March 2017 and received feedback in June 2017. We 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.

Market Opportunity

Our clinical program is intended to address the lack of successful treatments for SCIs, which can lead to permanent paralysis, sensory impairment, and autonomic (bowel, bladder, and sexual) dysfunction. The current management of acute SCI is a surgical approach consisting of spine stabilization and an external decompression that do not address repair of the spinal cord. We believe the market opportunity for our *Neuro-Spinal Scaffold* implant is significant. The National Spinal Cord Injury Statistical Center has estimated that approximately 285,000 people are

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currently living in the United States with paralysis due to SCI (chronic SCI), and InVivo estimates approximately 15,000 individuals in the United States will become fully or partially paralyzed each year (acute SCI).

We are pursuing regulatory approval from the U.S. Food and Drug Administration, or FDA, through the Humanitarian Device Exemption, or HDE, pathway. When this pathway was initiated for the *Neuro-Spinal Scaffold* implant, it was limited to populations of 4,000 or less patients per year. We were granted a Humanitarian Use Device, or HUD, designation for the *Neuro-Spinal Scaffold* implant, which includes thoracic and cervical patients afflicted with complete (no motor or sensory function in the lowest sacral segments) SCI, such as paraplegia or tetraplegia, and excludes gunshot or other penetrating wounds. Recently, the 21st Century Cures Act increased the upper population limit for an HDE from 4,000 to 8,000, which allows us to potentially request an expansion of our current HUD to include additional SCI patients, i.e., incomplete (partial sensory or sensory/motor function below the injury site, including the lowest sacral segments) SCI patients. Future products, which may include use of stem cells or drug ingredients, may enable the treatment of a broader population such as patients with chronic paralysis and would require separate regulatory approval.

Recent Developments

On April 16, 2018, our articles of incorporation were amended to effect a 1-for-25 reverse split of our common stock (the 2018 Reverse Split) On June 1, 2018, our articles of incorporation were further amended to increase the number of authorized shares of our common stock from 4,000,000 to 25,000,000 shares of common stock. All share and per share numbers included in this prospectus give effect to the 2018 Reverse Split.

On May 30, 2018, our shareholders approved the potential issuance of up to 1,200,000 shares of our common stock in a private placement at a price per share lower than the greater of book or market value of our shares of common stock on January 25, 2018, the date we entered into a purchase agreement with Lincoln Park Capital Fund, LLC, or the Purchase Agreement.

Risks Associated with Our Business and this Offering

Our business is subject to numerous risks and uncertainties, including those highlighted in the section entitled Risk Factors immediately following this prospectus summary. These risks include, but are not limited to, the following:

- 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. We may not be able to raise the funds to complete a clinical path, which may cause us to curtail or cease operations.

- If we are unable to raise capital when needed, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts.

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

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

- 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.

- 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 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.

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

- 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.

- 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.

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

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

- Our management team may invest or spend the proceeds raised in this offering in ways you may not agree or which may not yield a significant return.

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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		
Securities offered by us in this offering:		388,403 shares of our common stock and Series A warrants to purchase 388,403 shares of common stock, and Series B pre-funded warrants to purchase 6,242,811 shares of common stock and Series A warrants to purchase 6,242,811 shares of common stock.
Description of Series A warrants:		The shares and Series A warrants will be separately transferable immediately upon issuance, but the shares and Series A warrants will be issued and sold to purchasers in the ratio of one to one. Each Series A warrant will have an exercise price of $2.00 per share, will be exercisable upon issuance and will expire five years from the date of issuance.
Description of Series B pre-funded warrants:		If the issuance of shares of our common stock to a purchaser in this offering would result in such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering, then such purchaser may purchase, if they so choose, in lieu of the shares of our common stock that would result in such excess ownership, a Series B pre-funded warrant to purchase shares of our common stock for a purchase price per share of common stock subject to such Series B pre-funded warrant equal to the per share public offering price for the common stock in this offering less $0.01. Each Series B pre-funded warrant will have an exercise price of $0.01 per share, will be exercisable upon issuance and will expire twenty years from the date of issuance. Purchasers of Series B pre-funded warrants will also receive Series A warrants as if such purchasers were buying shares of our common stock in this offering. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of these Series B pre-funded warrants.
Over-allotment Option		We have granted a 45-day option to the underwriter to purchase up to an additional 989,997 shares of common stock and/or 989,997 Series A warrants, from us at a purchase price of $2.00, less the underwriting discounts and commissions solely to cover over-allotments, if any.
Common stock outstanding after this offering		1,950,687 shares of common stock, or 2,940,684 shares of common stock if the underwriter exercises its option to purchase additional shares of common stock in full.
Use of proceeds		We intend to use the net proceeds from this offering for initiation of a new clinical study of our *Neuro-Spinal Scaffold* implant or for other business development

		activities, as well as for working capital and general corporate purposes. See Use of Proceeds on page 35 of this prospectus.
Dividend policy		We have never paid cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future.
Risk factors		See Risk Factors beginning on page 10 and the other information included elsewhere in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our equity securities.
Nasdaq Capital Market symbol		Our common stock is listed on the Nasdaq Capital Market under the symbol NVIV. There is no established trading market for the Series A

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		warrants or the Series B pre-funded warrants, and we do not expect a trading market to develop. We do not intend to list the Series A warrants or the Series B pre-funded warrants on any securities exchange or other trading market. Without a trading market, the liquidity of the Series A warrants or Series B pre-funded warrants will be extremely limited.

The number of shares of common stock to be outstanding immediately after this offering is based on 1,562,284 shares of our common stock outstanding as of March 31, 2018, and excludes:

- 86,419 shares of common stock issuable upon the exercise of warrants outstanding as of March 31, 2018 at a weighted average exercise price of $248.92 per share;

- 81,011 shares of common stock issuable upon the exercise of options at a weighted average exercise price of $146.70 per share and 16,700 shares of common stock issuable upon vesting of restricted stock units outstanding as of March 31, 2018 pursuant to our stock incentives plans (collectively, the Incentive Plan);

- 160,299 shares of common stock available for future issuance under the Incentive Plan and 401(k) plan as of March 31, 2018;

- 9,933 shares of common stock reserved for future sale under our employee stock purchase plan as of March 31, 2018;

- 86,065 shares of common stock issued since March 31, 2018, consisting of 83,330 shares sold to Lincoln Park Capital pursuant to a Purchase Agreement dated January 25, 2018 by and between Lincoln Park Capital and us and 2,735 shares issued in connection with our reverse stock split upon the rounding of shares in accordance with our articles of incorporation; and

- 6,631,214 shares of common stock issuable upon the exercise of Series A warrants to be issued to investors in this offering at an exercise price of $2.00 per share.

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SUMMARY CONSOLIDATED FINANCIAL DATA

The following summary consolidated financial data as of or for the three months ended March 31, 2018 and 2017 have been derived from our unaudited consolidated financial statements incorporated by reference in this prospectus. The following summary consolidated financial data as of or for the fiscal years ended December 31, 2017 and 2016 have been derived from our audited consolidated financial statements incorporated by reference in this prospectus. The historical financial data presented below is not necessarily indicative of our financial results in future periods. You should read the summary consolidated financial data together with our consolidated financial statements and the related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations and other information included elsewhere in this prospectus or otherwise incorporated by reference. Our consolidated financial statements are prepared and presented in accordance with U.S. generally accepted accounting principles. All share and per share numbers included in this section, and elsewhere in this prospectus, give effect to the 2018 Reverse Split.

	Three Months Ended March 31, unaudited		Year Ended December 31,	
	2018	2017	2017	2016
	(in thousands, except share and per share data)			
Statement of Operations Data:				
Operating Expenses				
Research and development	1,398	3,384	11,083	12,557
General and administrative	3,434	3,285	13,510	11,506
Total operating expenses	4,832	6,669	24,593	24,063
Operating loss	(4,832)	(6,669)	(24,593)	(24,063)
Other income (expense)				
Interest income/(expense)	18	37	115	32
Other income/(expense)	42			
Derivatives gain (loss)	(12)	241	(2,267)	593
Other income (expense), net	48	278	(2,152)	625
Net loss	$ (4,784)	$ (6,391)	$ (26,745)	$ (23,438)
Net loss per share attributable to common stockholders, basic and diluted	$ (3,34)	$ (4,98)	$ (20.29)	$ (18.89)
Weighted average shares used to compute basic and diluted net loss per share attributable to common stockholders	1,432,963	1,283,206	1,318,003	1,241,024

	As of March 31, 2018	
	Actual	As Adjusted(a)
	(in thousands)	
Balance Sheet Data:		
Cash and cash equivalents	$ 11,614	$ 23,349
Total assets	$ 13,291	$ 25,026
Total liabilities	$ 4,968	$ 4,968
Accumulated deficit	$ (188,691)	$ (188,691)
Total stockholders equity	$ 8,323	$ 20,058 (b)

(a) As adjusted to give effect to the sale by us of 388,403 shares of common stock and Series A warrants to purchase 388,403 shares of common stock in this offering at a combined public offering price of $2.00 and Series B pre-funded warrants to purchase 6,242,811 shares of common stock in this offering and Series A warrants to purchase 6,242,811 shares of common stock at a combined public offering price of $1.99, after deducting the estimated underwriting discounts and commissions and estimated offering expenses, and excluding the proceeds, if any, from the exercise of Series A warrants and Series B pre-funded warrants issued in this offering.

(b) The As Adjusted amounts reflect the classification of the net proceeds from this offering as equity; however the Company has not yet completed its accounting analysis of the transaction or the allocation of value among the securities issued, in accordance with U.S. Generally Accepted Accounting Principles.

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RISK FACTORS

The following risk factors, together with all of the other information included or incorporated in this prospectus, should be carefully considered. If any of the following risks, either alone or taken together, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

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. We may not be able to raise the funds to complete a clinical path, 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, and we subsequently closed enrollment in The INSPIRE Study. Following our clinical trial hold in July 2017, we engaged in discussions with the FDA to define a clinical path forward. As part of the discussions with the FDA, we proposed, and FDA has approved, a randomized controlled trial to supplement the existing clinical evidence for the *Neuro-Spinal Scaffold* implant. We refer to this herein as the INSPIRE 2.0 Study. We cannot be certain that we will be able to raise the funds necessary for the clinical path forward.

Our financial statements as of March 31, 2018 were prepared under the assumption that we will continue as a going concern. At March 31, 2018, we had cash and cash equivalents of $11.6 million. In the event we are unable to obtain additional equity or debt financing, we will be unable to fund our operations for a meaningful time beyond the end of 2018.

Our current cash resources will not be sufficient to complete clinical development of our *Neuro-Spinal Scaffold* implant. If we are unable to raise capital, we may be forced to cease our operation entirely. 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.

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 12, 2018 included in our Annual Report on Form 10-K for the year ended December 31, 2017, which is incorporated by reference herein.

If we are unable to raise capital when needed, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts.

We expect our expenses will increase in connection with our ongoing activities, particularly if we undertake our planned INSPIRE 2.0 Study, 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.

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

- the scope, progress, results, and costs of preclinical development, laboratory testing, and clinical trials for our *Neuro-Spinal Scaffold* implant and any other product candidates that we may develop or acquire, including our planned INSPIRE 2.0 Study;

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

- the timing of, and the costs involved in, obtaining regulatory approvals for the *Neuro-Spinal Scaffold* implant, and the outcome of regulatory review of the *Neuro-Spinal Scaffold* implant;

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

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

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

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

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

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

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

- the efforts and activities of competitors and potential competitors;

- the effect of competing technological and market developments; and

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

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive, and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, 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 $4.8 million for the three months ended March 31, 2018 and of $26.7 million for the year ended December 31, 2017 and $23.4 million for the year ended December 31, 2016. As of March 31, 2018, we had an accumulated deficit of $188.7 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

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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 NOLs to 80% of current year taxable income and elimination of NOL carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such NOLs may be carried forward indefinitely), one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how

various states will respond to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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

We continue to actively evaluate business partnerships and acquisitions of businesses, technologies, or intellectual property rights that we believe would be necessary, useful, or complementary to our current business. Any such acquisition may require assimilation of the operations, products or product candidates, and personnel of the acquired business and the training and integration of its employees, and could substantially increase our operating costs, without any offsetting increase in revenue. We may also acquire the right to use certain intellectual property through licensing agreements, which could substantially increase our operating costs. Acquisitions and licensing agreements may not provide the intended technological, scientific or business benefits and could disrupt our operations and divert our limited resources and management s attention from our current operations, which could harm our existing product development efforts. While we may use cash or equity to finance a future acquisition or licensing agreement, it is likely we would issue equity securities as a significant portion or all of the consideration in any acquisition. The issuance of equity securities for an acquisition could be substantially dilutive to our stockholders. Any investment made in, or funds advanced to, a potential acquisition target could also significantly, adversely affect our results of operations and could further reduce our limited capital resources. Any acquisition or action taken in anticipation of a potential acquisition or other change in business activities could substantially depress the price of our stock. In addition, our results of operations may suffer because of acquisition related costs, or the post-acquisition costs of funding the development of an acquired technology or product candidates or operations of the acquired business, or due to amortization or impairment costs for acquired goodwill and other intangible assets.

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

We are wholly dependent on the success of one product candidate, the Neuro-Spinal Scaffold implant. Even if we are able to complete clinical development and obtain favorable clinical results, we may not be able to obtain regulatory approval for, or successfully commercialize, our Neuro-Spinal Scaffold implant.

We currently have only one product candidate, the *Neuro-Spinal Scaffold* implant, in clinical development, and our business depends almost entirely on the successful clinical development, regulatory approval, and commercialization of that product candidate, which may never occur. We currently have no products available for sale, generate no revenues from sales of any products, and we may never be able to develop marketable products. Our *Neuro-Spinal Scaffold* implant will require substantial additional clinical development, testing, manufacturing process development, and regulatory approval before we are permitted to commence its commercialization. Before obtaining regulatory approval via the 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 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 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.

Before we can obtain regulatory approval for the sale of our *Neuro-Spinal Scaffold* implant, we must complete the clinical studies that are required. In July 2017, The INSPIRE Study of our *Neuro-Spinal Scaffold* implant was placed on hold following the third patient death in the trial. We subsequently closed

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enrollment in The INSPIRE Study and will follow the active patients until completion. We have proposed, and the FDA has approved, the INSPIRE 2.0 Study. We may not be able to pursue the currently defined clinical path forward successfully, or in a timely manner or that is aligned with our cash resources. If we initiate the INSPIRE 2.0 Study to supplement the existing clinical evidence for the *Neuro-Spinal Scaffold* implant, 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 IRBs at each clinical site.

In addition, our results may subsequently fail to meet the safety and probable benefit standards required to obtain regulatory approvals. For example, in The INSPIRE Study, two of the 16 evaluable patients were initially assessed to have improved from complete AIS A SCI to incomplete AIS B SCI, but each was later assessed to have reverted to complete AIS A SCI prior to the patient s six-month examination. Of these two patients, one patient had converted back to AIS B and the other remained at AIS A at the six-month examination. There is known and published variability in some of the measures used to assess AIS improvement and these measures can vary over time or depending upon the examiner. While we implemented procedures in The INSPIRE Study and will also implement procedures in any future clinical study, including the INSPIRE 2.0 Study, to limit such variations, we cannot be certain that regulatory authorities will accept the results of our clinical trials or interpret them the way that we do.

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

- obtain regulatory approval to commence future clinical trials;
- reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtain IRB approval at each site;
- recruit, enroll, and retain patients through the completion of clinical trials;
- maintain clinical sites in compliance with trial protocols through the completion of clinical trials;
- address patient safety concerns that arise during the course of the trial;

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

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

We could encounter delays if a clinical trial is suspended or terminated by us, by the relevant IRB at the sites at which such trials are being conducted, by the Data Safety Monitoring Board for such trial, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, a problematic inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse events, or changes in laws or regulations. In addition, regulatory agencies may require an audit with respect to the conduct of a clinical trial, which could cause further delays or increase costs. For example, in December 2017, we and several of our clinical sites and our CRO were subject to an FDA inspection in association with The INSPIRE Study. At the close of the inspection at InVivo, the FDA issued a Form 483 with two observations relating to our over oversight of clinical trial sites in The INSPIRE Study. We sought, and will continue to seek, input from the FDA regarding the scope and timing of our proposed remediation efforts and the FDA has indicated that our corrective actions appear adequate. We cannot be certain that we will not be subject to additional regulatory action by the FDA. We anticipate that our remediation efforts will add costs to our clinical development plans. Any delays in completing our clinical trials will increase

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our costs, slow down our product candidate development and regulatory review process, and jeopardize our ability to obtain approval and commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, and prospects significantly.

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

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

Patient enrollment is affected by a number of factors including:

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

- patient referral practices of physicians; and

- ability to monitor patients adequately during and after treatment.

For a period in 2016, as a result of an FDA pre-specified enrollment hold, we were unable to enroll patients in The INSPIRE Study pending FDA authorization to proceed with additional enrollment, which delayed our ability to open new sites and enroll patients at the pace we had anticipated. In addition, in July 2017 we halted enrollment in the study, and subsequently closed enrollment in the study. We may experience similar delays with our planned INSPIRE 2.0 Study. We may not be able to initiate or continue clinical studies if we cannot enroll a sufficient number of eligible patients to participate in the clinical studies required by regulatory agencies. If we have difficulty enrolling a sufficient number of patients to conduct our clinical studies as planned, we may need to delay, limit, or terminate ongoing or planned clinical studies, any of which would have an adverse effect on our business.

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

The results of preclinical studies and early clinical trials of new medical devices do not necessarily predict the results of later-stage clinical trials. The design of our clinical trials is based on many assumptions about the expected effects of our product candidates, and if those assumptions are incorrect, the trials may not produce results to support regulatory approval. We are currently pursuing marketing approval via the HDE regulatory pathway which requires us to show the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit of health outweighs the risk of injury or illness from its use. Preliminary results may not be confirmed upon full analysis of the detailed results of an early clinical trial. Product candidates in later stages of clinical development may fail to show safety and probable benefit sufficient to support intended use claims despite having progressed

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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.

The development, manufacture, and marketing of our products are subject to government regulation in the United States and other countries. In the United States and most foreign countries, we must complete rigorous preclinical testing and extensive human clinical trials that demonstrate the safety and efficacy of a product in order to apply for regulatory approval to market the product. If the FDA grants regulatory approval of a product, the approval may be limited to specific indications or limited with respect to its distribution. Expanded or additional indications for approved devices may not be approved, which could limit our potential revenues. Foreign regulatory authorities may apply similar or additional limitations or may refuse to grant any approval. Consequently, even if we believe that preclinical and clinical data are sufficient to support regulatory approval for our products, the FDA and foreign regulatory authorities may not ultimately grant approval for commercial sale in any jurisdiction. If our product candidates are not approved, our ability to generate revenues will be limited and our business will be adversely affected.

We are currently pursuing an HDE regulatory pathway in the United States for our *Neuro-Spinal Scaffold* implant. The HDE requires that there is no other comparable device available to provide therapy for a condition and requires sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use. The amended protocol for The INSPIRE Study, which was approved in February 2016, established an OPC, which is a measure of study success used in clinical studies designed to demonstrate safety and probable benefit in support of an HDE approval. The OPC for The INSPIRE Study is currently defined as 25% or more of the patients in the study demonstrating an improvement of at least one AIS grade by six months post-implantation. While we expect The INSPIRE Study to serve as one source of data used to supp