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 support HDE approval in the future, we will not complete full enrollment of that study. In addition, although The INSPIRE Study is structured with the OPC as the primary component for demonstrating probable benefit, the OPC is not the only variable that the FDA would evaluate when reviewing a future HDE application.

The FDA had previously recommended that we include a randomized, concurrent control arm in the study and we have proposed and received approval for the INSPIRE 2.0 Study. The primary endpoint is defined as the proportion of patients achieving an improvement of at least one AIS grade at six months post-implantation. The definition of study success is that the difference in the proportion of subjects who demonstrate an improvement of at least one grade on AIS assessment at the six-month primary endpoint follow-up visit between the Scaffold Arm and the Comparator Arm must be equal to or greater than 20%. While our planned INSPIRE 2.0 Study is structured with a definition of study success requiring a minimum difference between groups in the percentage of subjects achieving improvement, that success definition is not the only factor that the FDA would evaluate in the future HDE application.

Approval is not guaranteed if the OPC is met for The INSPIRE Study or the definition of study success is met for the INSPIRE 2.0 Study, and even if the OPC or definition of study success are not met, the FDA may approve a medical device if probable benefit is supported by a comprehensive review of all clinical endpoints and preclinical results, as demonstrated by the sponsor s body of evidence.

In addition, as one source of comparator data, we initiated the CONTEMPO Registry Study, utilizing existing databases and registries to develop a historical comparator that, to the extent possible, matches patients to those patients enrolled in The INSPIRE Study. There can be no assurance that either our planned INSPIRE 2.0 Study or the CONTEMPO Registry Study will be successfully completed. Even if we successfully complete the INSPIRE 2.0 Study and the CONTEMPO Registry Study, we cannot be certain that the FDA will agree that these

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additional studies provide sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use. Moreover, analysis of data from the CONTEMPO Registry Study may suggest a higher threshold for evidencing probable benefit. For example, AIS conversion rates at approximately six months post-injury across the three registries used in CONTEMPO varied from 16.7% 23.4%, which are higher than the approximately 15.5% conversion rate from the historical registries that were the basis for the selection of the current OPC for The INSPIRE Study. In the event our clinical data is not acceptable to the FDA, our ability to obtain approval under the HDE pathway may be delayed or may not be feasible. If the FDA does not approve our product candidates in a timely fashion, or at all, our business and financial condition will be adversely affected.

The 21st Century Cures Act recently increased the upper population limit for an HDE from 4,000 to 8,000, which allows us to potentially request an expansion of our current HUD to include additional patient populations beyond our current HUD for complete SCI. If we choose to pursue such an expansion, this may cause our application to be delayed or cause the FDA to request additional information. In addition, our current study is not designed to support approval beyond complete SCI. Thus, expansion would require additional studies. We cannot be certain that we will be able to increase the potential population that we might be able to treat based on the HDE pathway. If any of these events occur, our business and financial condition will be adversely affected.

There are risks associated with pursuing FDA approval via an HDE pathway, including the possibility that the approval could be withdrawn in the future if the FDA subsequently approves another device for the same intended use, as well as limitations on the ability to profit from sales of the product.

If the FDA subsequently approves a PMA or clears a 510(k) for the HUD or another comparable device with the same indication, the FDA may withdraw the HDE. Once a comparable device becomes legally marketed through PMA approval or 510(k) clearance to treat or diagnose the disease or condition in question, there may no longer be a need for the HUD and so the HUD may no longer meet the requirements of section 520(m)(2)(B) of the FDCA.

Except in certain circumstances, products approved under an HDE cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (i.e., for profit). Currently, under section 520(m)(6)(A)(i) of the FDCA, as amended by the Food and Drug Administration Safety and Innovation Act, an HUD is only eligible to be sold for profit after receiving HDE approval if the device (1) is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or (2) is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe. If an HDE-approved device does not meet either of the eligibility criteria, the device cannot be sold for profit. With enactment of the FDA Reauthorization Act of 2017, Congress provided that the exemption for HUD / HDE profitability is available as long as the request for an exemption is submitted before October 1, 2022.

Some of our future products may be viewed by the FDA as combination products and the review of combination products is often more complex and more time consuming than the review of other types of products.

Our future products may be regulated by the FDA as combination products. For a combination product, the FDA must determine which center or centers within the FDA will review the product candidate and under what legal authority the product candidate will be reviewed. The process of obtaining FDA marketing clearance or approval is lengthy, expensive, and uncertain, and we cannot be sure that any of our combination products, or any other products, will be cleared or approved in a timely fashion, or at all. In addition, the review of combination products is often

more complex and more time consuming than the review of a product candidate under the jurisdiction of only one center within the FDA. We cannot be sure that the FDA will not select to have our combination products reviewed and regulated by only one FDA center and/or different legal authority, in which case the path to regulatory approval would be different and could be more lengthy and costly. If the FDA does not approve or clear our products in a timely fashion, or at all, our business and financial condition will be adversely affected.

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

In general, the biotechnology industry is subject to intense competition and rapid and significant technological change. We have many potential competitors, including major drug companies, specialized biotechnology firms, academic institutions, government agencies, and private and public research institutions. Many of these competitors have significantly greater financial and technical resources than us, and superior experience and expertise in research and development, preclinical testing, design and implementation of clinical trials, regulatory processes and approval for products, production and manufacturing, and sales and marketing of approved products. Large and established companies compete in the biotechnology market. In particular, these companies have greater experience and expertise in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale, and marketing approved products. Smaller or early-stage companies and research institutions may also prove to be significant competitors, particularly if they have collaborative arrangements with larger and more established biotechnology companies. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, and registering subjects for clinical trials.

In order to effectively compete, we will have to make substantial investments in development, clinical testing, manufacturing, and sales and marketing, or partner with one or more established companies. There is no assurance that we will be successful in having our products approved or gaining significant market share for any of our products. Our technologies and products also may be rendered obsolete or noncompetitive as a result of products introduced by our competitors.

The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.

Our ongoing research and development, preclinical testing, and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. Clinical studies must be conducted in compliance with FDA regulations or the FDA may take enforcement action. The data collected from these clinical studies may ultimately be used to support market clearance for these products. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA will agree with our conclusions regarding them. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and preclinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate s profile.

If approved, our products will require market acceptance to be successful. Failure to gain market acceptance would impact our revenues and may materially impair our ability to continue our business.

Even if we receive regulatory approvals for the commercial sale of our product candidates, the commercial success of our products will depend on, among other things, their acceptance by physicians, patients, third-party payers such as health insurance companies, and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. Physicians and hospitals will need to establish training and procedures to utilize and implement our *Neuro-Spinal Scaffold* implant, and there can be no assurance that these parties will adopt the use of our device or develop sufficient training and procedures to properly utilize it. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, both within and outside of our control. Payers may view new

products or products that have only recently been launched or with limited clinical data available, as investigational, unproven, or experimental, and on that basis may deny coverage of procedures involving use of our products. If our product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business.

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If we or our suppliers fail to comply with FDA regulatory requirements, or if we experience unanticipated problems with any approved products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain regulatory approval, and the manufacturing processes, reporting requirements, post-approval clinical data, and promotional activities for such product, will be subject to continued regulatory review and oversight by the FDA. In particular, we and our third-party suppliers will be required to comply with the FDA s Quality System Regulations, or QSRs. These FDA regulations cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage, and shipping of products. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. If we, or our manufacturers, fail to adhere to QSR requirements, this could delay production of our product candidates and lead to fines, difficulties in obtaining regulatory clearances, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition and results of operations.

In addition, we and our suppliers are required to comply with Good Manufacturing Practices and Good Tissue Practices with respect to any human cells and biologic products we may develop, and International Standards Organization regulations for the manufacture of our products, and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, and shipping of any product for which we obtain clearance or approval. Manufacturing may also be subject to controls by the FDA for parts of the combination products that the FDA may find are controlled by the biologics regulations.

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

- untitled letters, warning letters, fines, injunctions, consent decrees, and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention, or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for premarket approval of new products or modified products;

- withdrawing PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

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

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

Our medical device and biologic products and operations are subject to extensive regulation by the FDA and various other federal, state, and foreign governmental authorities. For example, we expect to initiate a clinical trial in Canada and will be subject to applicable Canadian regulations as we initiate and conduct that trial.

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Government regulation of medical devices and biologic products is meant to assure their safety and effectiveness, and includes regulation of, among other things:

- design, development, and manufacturing;
- testing, labeling, content, and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales, and distribution;
- regulatory clearances and approvals including premarket clearance and approval;
- conformity assessment procedures;
- product traceability and record keeping procedures;
- advertising and promotion;
- product complaints, complaint reporting, recalls, and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries, and malfunctions that, if they were to recur, could lead to death or serious injury;

- post-market studies; and

- product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could impede our ability to carry on or expand our operations and could result in higher than anticipated costs or lower than anticipated sales.

Before we can market or sell a new regulated medical device product in the United States, we must obtain clearance under Section 510(k) of the FDCA, approval of a PMA, or approval of an HDE, unless the device is specifically exempt from premarket review. Our *Neuro-Spinal Scaffold* implant is expected to be regulated by the FDA as a Class III medical device, requiring either PMA or HDE approval. An HUD designation was granted for the *Neuro-Spinal Scaffold* implant in 2013, opening the HDE pathway.

In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing, and labeling data.

Modifications to products that are approved through a PMA generally need FDA approval. The process of obtaining a PMA is costly and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA until an approval is obtained.

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

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

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

- we may not be able to demonstrate to the FDA s satisfaction that our products are safe and effective for their intended uses;

- the data from our preclinical studies and clinical trials may be insufficient to support clearance or approval, where required; and

- the manufacturing process or facilities we use may not meet applicable requirements.

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

Further, even after we have obtained the proper regulatory clearance or approval to market a product, the FDA may require us to conduct post-marketing studies. Failure to conduct required studies in a timely manner could result in the revocation of approval for the product that is subject to such a requirement and could also result in the recall or withdrawal of the product, which would prevent us from generating sales from that product in the United States.

Failure to comply with applicable laws and regulations could jeopardize our ability to sell our products and result in enforcement actions such as:

- warning letters;

- fines;

- injunctions;
- civil penalties;
- termination of distribution;
- recalls or seizures of products;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- refusal of the FDA or other regulators to grant future clearances or approvals;
- withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and/or
- in the most serious cases, criminal penalties.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, results of operations, and financial condition.

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If our products, or the malfunction of our products, cause or contribute to a death or a serious injury before or after approval, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

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

Our products, once approved, may in the future be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

If our products are approved for commercialization, the FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the decision to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. A government-mandated or voluntary recall by us or one of our partners could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects, or other deficiencies and issues. Recalls of any of our commercialized products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations, and financial condition, which could impair our ability to manufacture our products in a cost-effective and timely manner in order to meet our customers demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits.

If we obtain approval for our products, we may be subject to enforcement action if we engage in improper marketing or promotion of our products.

We are not permitted to promote or market our investigational products. After approval, our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or off-label, use. Surgeons may use our products off-label, as the FDA does not restrict or regulate a surgeon s choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine, or criminal penalties. It is also possible that other federal, state, or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products could be impaired. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management s attention, result in substantial damage awards against us, and harm our reputation.

If we obtain approval for our products, their commercial success will depend in part upon the level of reimbursement we receive from third parties for the cost of our products to users.

The commercial success of any product will depend, in part, on the extent to which reimbursement for the costs of our products and related treatments will be available from third-party payers such as government health administration authorities, private health insurers, managed care programs, and other organizations. Adequate third-party insurance coverage may not be available for us to establish and maintain price levels that are sufficient for us to continue our business or for realization of an appropriate return on investment in product development.

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Legislative or regulatory reform of the healthcare systems in which we operate may affect our ability to commercialize our product candidates and could adversely affect our business.

The government and regulatory authorities in the United States, the European Union, and other markets in which we plan to commercialize our product candidates may propose and adopt new legislation and regulatory requirements relating to the approval, CE marking, manufacturing, promotion, or reimbursement of medical device and biologic products. It is impossible to predict whether legislative changes will be enacted or applicable regulations, guidance, or interpretations changed, and what the impact of such changes, if any, may be. Such legislation or regulatory requirements, or the failure to comply with such, could adversely impact our operations and could have a material adverse effect on our business, financial condition, and results of operations.

For example, in the United States, legislative changes have been enacted in the past and further changes are proposed that would impact the Affordable Care Act. These new laws may result in additional reductions in Medicare and other healthcare funding. Beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, on average, to 2025. It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing healthcare legislation. The Affordable Care Act has faced ongoing legal challenges, including litigation seeking to invalidate some of or all of the law or the manner in which it has been implemented. With the new Presidential administration and Congress, there have been, and may be additional, legislative changes affecting the Affordable Care Act, including repeal of certain provisions of the Affordable Care Act. It remains to be seen, however, precisely what impact legislation to date and any future legislation will have on the availability of healthcare and containing or reducing healthcare costs. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. We cannot quantify or predict with any certainty the likely impact of the Affordable Care Act, its amendment or repeal, or any alternative or related legislation, or any implementation of any such legislation, on our business model, prospects, financial condition, and results of operations.

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

We have limited experience manufacturing our Neuro-Spinal Scaffold implant for clinical-study scale and no experience for commercial scale.

To date, we have manufactured our *Neuro-Spinal Scaffold* implant on a small scale, including sufficient supply that is needed for our clinical studies. We may encounter unanticipated problems in the scale-up process that will result in delays in the manufacturing of the *Neuro-Spinal Scaffold* implant and therefore delay our clinical studies. During our clinical trials, we are subject to FDA regulations requiring manufacturing of our scaffolds with the FDA requirements for design controls and subject to inspections by regulatory agencies. Our failure to comply with applicable regulations may result in delays and interruptions to our product supply while we seek to secure another supplier that meets all regulatory requirements. If we are unable to scale up our manufacturing to meet requirements for our clinical studies, we may be required to rely on contract manufacturers. Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product ourselves, including the possible breach of the manufacturing agreements by the third parties because of factors beyond our control, and the possibility of termination or nonrenewal of the agreements by the third parties because of our breach of the manufacturing agreement or based on their own business priorities.

Risks Related to Our Intellectual Property

We license certain technology underlying the development of our Neuro-Spinal Scaffold implant from BCH and MIT, and the loss of the license would result in a material adverse effect on our business, financial position, and operating results and cause the market value of our common stock to decline.

We license technology from Boston Children s Hospital, or BCH, and the Massachusetts Institute of Technology, or MIT, that is integrated into our *Neuro-Spinal Scaffold* implant under an exclusive license. Under the license agreement, we have agreed to milestone payments and to meet certain reporting obligations. In the event that

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we were to breach any of the obligations under the agreement and fail to timely cure, BCH and MIT would have the right to terminate the agreement upon notice. In addition, BCH and MIT have the right to terminate our license upon the bankruptcy or receivership of the Company. If we are unable to continue to use or license this technology on reasonable terms, or if this technology fails to operate properly, we may not be able to secure alternatives in a timely manner and our ability to develop our products could be harmed.

If we cannot protect, maintain and, if necessary, enforce our intellectual property rights, our ability to develop and commercialize products will be adversely impacted.

Our success, in large part, depends on our ability to protect and maintain the proprietary nature of our technology. We and our licensors must prosecute and maintain our existing patents and obtain new patents. Some of our proprietary information may not be patentable, and there can be no assurance that others will not utilize similar or superior solutions to compete with us. We cannot guarantee that we will develop proprietary products that are patentable, and that, if issued, any patent will give a competitive advantage or that such patent will not be challenged by third parties. The process of obtaining patents can be time consuming with no certainty of success, as a patent may not issue or may not have sufficient scope or strength to protect the intellectual property it was intended to protect. We cannot assure you that our means of protecting our proprietary rights will suffice or that others will not independently develop competitive technology or design around patents or other intellectual property rights issued to us. Even if a patent is issued, it does not guarantee that it is valid or enforceable. Any patents that we or our licensors have obtained or obtain in the future may be challenged, invalidated, or unenforceable. If necessary, we may initiate actions to protect our intellectual property, which can be costly and time consuming.

If third parties successfully claim that we infringe their intellectual property rights, our ability to continue to develop and commercialize products could be delayed or prevented.

Third parties may claim that we or our licensors are infringing on or misappropriating their proprietary information. Other organizations are engaged in research and product development efforts that may overlap with our products. Such third parties may currently have, or may obtain in the future, legally blocking proprietary rights, including patent rights, in one or more products or methods under development or consideration by us. These rights may prevent us from commercializing products, or may require us to obtain a license from the organizations to use the technology. We may not be able to obtain any such licenses that may be required on reasonable financial terms, if at all, and cannot be sure that the patents underlying any such licenses will be valid or enforceable. There may be rights that we are not aware of, including applications that have been filed but not published that, when issued, could be asserted against us. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research and development of the product that is the subject of the suit. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our trade secrets or other confidential information could be compromised by disclosure during this type of litigation.

Risks Related to our Dependence on Third Parties

We will depend upon strategic relationships to develop, exploit, and manufacture our products. If these relationships are not successful, we may not be able to capitalize on the market potential of these products.

The near and long-term viability of our products will depend, in part, on our ability to successfully establish new strategic collaborations with biotechnology companies, hospitals, insurance companies, and government agencies.

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

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

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

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

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

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

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

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

Risks Related to Employee Matters and Managing Growth

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

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

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significantly delay or prevent the achievement of research, development, or business objectives. Competition for qualified employees is intense among biotechnology companies, and the loss of qualified employees, or an inability to attract, retain, and motivate additional highly skilled employees could hinder our ability to successfully develop marketable products.

Our future success also depends on our ability to identify, attract, hire, train, retain, and motivate other highly skilled scientific, technical, marketing, managerial, and financial personnel. Although we will seek to hire and retain qualified personnel with experience and abilities commensurate with our needs, there is no assurance that we will succeed despite our collective efforts. The loss of the services of any of our senior management or other key personnel could hinder our ability to fulfill our business plan and further develop and commercialize our products and services. Competition for personnel is intense, and any failure to attract and retain the necessary technical, marketing, managerial, and financial personnel would have a material adverse effect on our business, prospects, financial condition, and results of operations.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from collaborators, prospective licensees, and other third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees former employers. We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to Litigation and Legal Compliance

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

We are involved in litigation with our former Chairman, Chief Executive Officer, and Chief Financial Officer. We were previously the subject of a securities derivative lawsuit and a securities class action lawsuit, both of which were dismissed in January 2017. We may face additional lawsuits, including class action or securities derivative lawsuits. The amount of time that is required to resolve these lawsuits is unpredictable and any lawsuits may divert management s attention from the day-to-day operations of our business, which could adversely affect our business, results of operations, and cash flows. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. See Legal Proceedings in our quarterly report on Form 10-Q for the quarter ended March 31, 2018, incorporated by reference in this prospectus, for further information regarding our litigation.

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

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

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defending such a claim would be time-consuming and expensive, may damage our reputation in the marketplace, and would likely divert our management s attention.

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

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

Our relationships with customers and third party payers will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm, and diminished profits and future earnings.

Healthcare providers, physicians, and third party payers will play a primary role in the recommendation and use of our products and any other product candidates for which we obtain marketing approval. Our future arrangements with healthcare providers, physicians, and third party payers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order, or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

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

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

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

Some state laws require device companies to comply with the industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require product

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manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs.

Risks Related to This Offering and Our Common Stock

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

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

- the status, completion, and/or results of our clinical trials;
- actual or anticipated variations in our operating results;
- announcements of developments by us or our competitors;
- regulatory actions regarding our products;

- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;

- adoption of new accounting standards affecting our industry;

- additions or departures of key personnel;

- sales of our common stock or other securities in the open market; and

- other events or factors, many of which are beyond our control.

The stock market is subject to significant price and volume fluctuations. In the past, following periods of volatility in the market price of a company s securities, securities class action litigation has often been initiated against such company. Litigation initiated against us, whether or not successful, could result in substantial costs and diversion of our management s attention and resources, which could harm our business and financial condition.

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

Our management will have broad discretion over the use of proceeds from this offering. Assuming that the amount we raise is sufficient to complete enrollment in the Inspire 2.0 Study, we will use the proceeds to initiate that trial and explore business development opportunities. Based on the net proceeds to us after deducting underwriting discounts and commissions and estimated offering expenses, we would not have sufficient proceeds to complete enrollment in the Inspire 2.0 Study, and would need to raise additional capital or use our existing cash reserves to complete enrollment in the trial. If the proceeds, or the combination of the proceeds and our existing cash reserves, are not sufficient to initiate the trial and we elect not to initiate the trial, we intend to use the net proceeds from this offering for business development opportunities, and for working capital and general corporate purposes. Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline, and delay the development of our product candidates.

There is no public market for the Series A warrants or the Series B pre-funded warrants being offered by us in this offering.

There is no established public trading market for the Series A warrants or the Series B pre-funded warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list the Series A warrants or the Series B pre-funded warrants on any national securities exchange or other nationally recognized trading system, including the Nasdaq Capital Market. Without an active market, the liquidity of the Series A warrants and the Series B pre-funded warrants will be limited.

Holders of Series B pre-funded warrants or Series A warrants purchased in this offering will have no rights as common stockholders until such holders exercise their Series B pre-funded warrants or Series A warrants and acquire our common stock, except as otherwise provided in the Series B pre-funded warrants.

Until holders of Series B pre-funded warrants or Series A warrants acquire shares of our common stock upon exercise thereof, such holders will have no rights with respect to the shares of our common stock underlying the Series B pre-funded warrants and Series A warrants, except to the extent that holders of the Series B pre-funded warrants will have certain rights to participate in distributions or dividends paid on our common stock as set forth in the Series B pre-funded warrants. Upon exercise of the Series B pre-funded warrants or Series A warrants, the

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holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

The Series A warrants are speculative in nature.

The Series A warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the Series A warrants may exercise their right to acquire the common stock and pay an exercise price of $2.00 per share of common stock, subject to certain adjustments, prior to five years from the date of issuance in the case of the Series A warrants, after which date any unexercised Series A warrants will expire and have no further value. Moreover, following this offering, the market value of the Series A warrants, if any, is uncertain and there can be no assurance that the market value of the Series A warrants will equal or exceed their imputed offering price. The Series A warrants will not be listed or quoted for trading on any market or exchange. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the Series A warrants, and consequently, it may not ever be profitable for holders of the Series A warrants to exercise such warrants.

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

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

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

Our common stock is listed on the Nasdaq Capital Market. For continued listing on the Nasdaq Capital Market, we will be required to comply with the continued listing requirements, including the minimum market capitalization standard, the corporate governance requirements and the minimum closing bid price requirement, among other requirements. For example, on January 23, 2018 we received a deficiency letter from the Listings Qualifications Department of the Nasdaq Stock Market notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued inclusion on the Nasdaq Global Market. Although we have regained compliance with the Bid Price Rule as a result of the reverse stock split we effected on April 16, 2018, we received a written notification from the Listing Qualifications Department of the Nasdaq Stock Market on May 11, 2018, notifying us that, based on our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, our stockholders equity was $8,323,000, and therefore, the we were not in compliance with the minimum stockholders equity standard which requires a minimum of $10,000,000 in stockholders equity. We have applied to transfer our listing to the Nasdaq Capital Market. As a result, we elected to transfer to the Nasdaq Capital Market, and the transfer was effective June 19, 2018. In the event that we fail to satisfy any of the listing requirements of the Nasdaq Capital Market our common stock may be delisted. If our securities are delisted from trading on the Nasdaq Capital Market, and we are not able to list our securities on another exchange our securities could be quoted on the OTC Bulletin Board or on the pink sheets. As a result, we could face significant adverse consequences including:

- a limited availability of market quotations for our securities;

- a determination that our common stock is a penny stock, which would require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;

- a limited amount of news and analyst coverage; and

- a decreased ability to issue additional securities (including pursuant to short-form registration statements on Form S-3 or obtain additional financing in the future).

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Anti-takeover effects of certain provisions of our articles of incorporation and Nevada state law may discourage or prevent a takeover.

Our articles of incorporation divide our Board of Directors into three classes, with three-year staggered terms. The classified board provision could increase the likelihood that, in the event an outside party acquired a controlling block of our stock, incumbent directors nevertheless would retain their positions for a substantial period, which may have the effect of discouraging, delaying, or preventing a change in control. In addition, Nevada has a business combination law, which prohibits certain business combinations between Nevada publicly traded corporations, or Nevada corporations that elect to be subject to the law, and interested stockholders for two years after the interested stockholder first becomes an interested stockholder, unless the corporation s board of directors approves the transaction by which the stockholder becomes an interested stockholder in advance, or the proposed combination in advance of the stockholder becoming an interested stockholder. The acquisition of any combination of shares of our common stock, Series A warrants, and/or Series B pre-funded warrants that would result in a holder s beneficial ownership (as defined by Nevada law) of more than 9.99% of our outstanding common stock or otherwise could cause such purchaser, its affiliates, or associates (each as defined by Nevada law) to be an interested stockholder.

The proposed combination may be approved after the stockholder becomes an interested stockholder with preapproval by the board of directors and a vote at a special or annual meeting of stockholders holding at least 60% of the voting power not owned by the interested stockholder or his/her/ its affiliates or associates. After the two-year moratorium period, additional stockholder approvals or fair value requirements must be met by the interested shareholder up to four years after the stockholder became an interested stockholder. In addition, we may become subject to Nevada s control share laws. A corporation is subject to Nevada s control share law if it has more than 200 stockholders, at least 100 of whom are stockholders of record and residents of Nevada, and if the corporation does business in Nevada, including through an affiliated corporation. This control share law may have the effect of discouraging corporate takeovers. Currently, we believe that we have less than 100 stockholders of record who are residents of Nevada, and are therefore not subject to the control share laws.

The provisions of our articles of incorporation and Nevada s business combination and control share laws make it more difficult for a third party to acquire us and make a takeover more difficult to complete, even if such a transaction were in our stockholders interest or might result in a premium over the market price for our common stock.

We may issue additional equity securities in the future, which may result in dilution to existing investors and investors purchasing securities in this offering.

We may seek the additional capital necessary to fund our operations through public or private equity offerings, debt financings, and collaborative and licensing arrangements. Although investors purchasing securities in this offering will not experience immediate dilution because the effective price per share of the common stock and related warrants is lower than the net tangible book value per share of our common stock, to the extent we raise additional capital by issuing equity securities, including in a debt financing where we issue convertible notes or notes with warrants and any shares of our common stock to be issued in a private placement, our stockholders may experience substantial dilution. We may, from time to time, sell additional equity securities in one or more transactions at prices and in a manner we determine. We cannot assure you that we will be able to sell shares of our common stock or other equity securities, including any Series A warrants or Series B pre-funded warrants, in any other offering at a price per fixed combination that is equal to or greater than the price per fixed combination paid by investors in this offering. The price per share at which we sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price per fixed combination in this offering. If we sell additional equity securities, existing stockholders may be materially diluted. In addition, new investors could gain rights superior to existing stockholders, such as liquidation and other preferences. In addition, the exercise or conversion of outstanding options or warrants to purchase shares of capital stock may result in dilution to our stockholders upon any such exercise or conversion.

In addition, as of March 31, 2018, 156,633 shares remained available to be awarded under our Incentive Plan. Further, an aggregate of 101,277 shares of our common stock could be delivered upon the exercise or conversion of outstanding stock options or restricted stock units under the Incentive Plan and other equity incentive plans we previously assumed. We may also issue additional options, warrants and other types of equity in the future as part of stock-based compensation, capital raising transactions, technology licenses, financings, strategic licenses, or other strategic transactions. To the extent these options are exercised, existing stockholders would experience additional ownership dilution.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain 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 include statements made regarding our commercialization strategy, future operations, cash requirements and liquidity, capital requirements, and other statements on our business plans and strategy, financial position, and market trends. In some cases, you can identify forward-looking statements by terms such as may, might, will, should, believe, plan, intend, anticipate, target, esti other similar expressions. These forward-looking statements are subject to risks and uncertainties that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements, including factors such as our ability to raise substantial additional capital to finance our planned operations and to continue as a going concern; our ability to execute our strategy and business plan; our ability to obtain regulatory approvals for our products, including the *Neuro-Spinal Scaffold*; our ability to successfully commercialize our current and future product candidates, including the *Neuro-Spinal Scaffold*; the progress and timing of our development programs; market acceptance of our products; our ability to retain management and other key personnel; our ability to promote, manufacture, and sell our products, either directly or through collaborative and other arrangements with third parties; and other factors detailed under Risk Factors . These forward-looking statements are only predictions, are uncertain, and involve substantial known and unknown risks, uncertainties, and other factors which may cause our actual results, levels of activity, or performance to be materially different from any future results, levels of activity, or performance expressed or implied by these forward-looking statements. Such factors include, among others, the following:

- 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 initiate and complete the INSPIRE 2.0 Study 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 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.

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We cannot guarantee future results, levels of activity, or performance. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this prospectus. These cautionary statements should be considered with any written or oral forward-looking statements that we may issue in the future. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to reflect actual results, later events or circumstances, or to reflect the occurrence of unanticipated events.

For a more detailed discussion of these and other that may affect our business and that could cause our actual results to differentiate equally from those projected in these forward-looking statements, see the risk factors and uncertainties described under the heading Risk Factors in this prospectus, in Part I, Item 1A of our Annual Report on Form 10-K filed with the SEC on March 12, 2018, and in Part II, Item 1A or our Quarterly Report on Form 10-Q filed with the SEC on May 7, 2018. The forward-looking statements contained in this prospectus and in any of the documents incorporated by reference are expressly qualified in their entirety by this cautionary statement. The events and circumstances reflected in the forward-looking statements may not be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events, except as required by law.

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USE OF PROCEEDS

The net proceeds from this offering will be approximately $11.7 million from the sale of our securities in this offering, based on the sale of (i) 388,403 shares of common stock and Series A warrants to purchase 388,403 shares of common stock at a combined public offering price of $2.00 per share of common stock and Series A warrant and (ii) 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 at a combined public offering price of $1.99 per Series B warrant and Series A warrant, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriter exercises its option to purchase the additional securities in full, we estimate the net proceeds from this offering will be approximately $13.6 million from the sale of our securities, assuming no exercise of Series A Warrants acquired upon exercise of the option and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

These estimates exclude the proceeds, if any, from the exercise of Series A warrants in this offering. If all of the Series A warrants sold in this offering were to be exercised in cash at the exercise price of $2.00 per whole share of common stock, we would receive additional proceeds of approximately $13.3 million, or additional net proceeds of approximately $1.8 million if the underwriter exercises its option to purchase the additional securities in full. We cannot predict when or if these Series A warrants will be exercised. It is possible that these Series A warrants may expire and may never be exercised. Additionally, the Series A warrants contain a cashless exercise provision that permit exercise of Series A warrants on a cashless basis at any time where there is no effective registration statement under the Securities Act of 1933, as amended, covering the issuance of the underlying shares.

We currently expect 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. We cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. Accordingly, our management will have broad discretion and flexibility in applying the net proceeds from the sale of securities sold pursuant to this prospectus. In addition, our existing resources, together with the proceeds from this offering, may not be adequate to permit us to initiate such a trial, engage in such business development activities, or fund our operations over the longer term. We may need to secure additional resources to initiate such a trial, engage in such business development activities, and to support our continued operations. Pending application of the net proceeds as described above, we intend to invest the net proceeds to us from this offering in a variety of capital preservation investments, including short-term, investment-grade and interest-bearing instruments.

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CAPITALIZATION

The following table sets forth our cash and cash equivalents, as well as our capitalization, as of March 31, 2018 as follows:

- on an actual basis; and

- 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 per share of common stock and Series A warrant, and the sale of 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 in this offering at a combined public offering price of $1.99 per Series B pre-funded warrant and Series A warrant, 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 issued in this offering.

You should read this information together with our consolidated financial statements and related notes incorporated by reference in this prospectus. All share and per share numbers included in this section, and elsewhere in this prospectus, give effect to the 2018 Reverse Split.

	As of March 31, 2018 (Unaudited)	
	Actual	As Adjusted
	(in thousands, except share amounts)	
Cash and cash equivalents	$ 11,614	$ 23,349
Loan payable	742	742
Stockholders equity		
Common stock, $0.00001 par value 4,000,000 shares authorized; 1,562,284 shares issued and outstanding, on an actual basis	1	1
Additional paid-in capital	197,013	208,748(a)
Accumulated deficit	(188,691)	(188,691)
Total stockholders equity	8,323	20,058
Total capitalization	$ 9,065	$ 20,800

(a) 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.

The information above 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;

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- 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 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; and

- 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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DESCRIPTION OF SECURITIES

Common Stock

We have authorized 25,000,000 shares of capital stock, par value $0.00001 per share, all of which are shares of common stock. As of March 31, 2018, there were 1,562,284 shares of common stock issued and outstanding. The authorized and unissued shares of common stock are available for issuance without further action by our stockholders, unless such action is required by applicable law or the rules of any stock exchange on which our securities may be listed. Unless approval of our stockholders is so required, our board of directors does not intend to seek stockholder approval for the issuance and sale of our common stock. All shares of common stock will, when issued, be duly authorized, fully paid and non-assessable. Accordingly, the full price for the outstanding shares of common stock will have been paid at issuance and any holder of our common stock will not be later required to pay us any additional money for such common stock.

The holders of our common stock are entitled to one vote per share. Generally, all matters to be voted on by stockholders must be approved by a majority (or, in the case of election of directors, by a plurality) of the votes entitled to be cast by all shares of common stock that are present in person or represented by proxy. Additionally, any alteration, amendment or appeal of any provision of our bylaws would require the affirmative vote of the holders of at least 80% of the voting power of the then outstanding shares of the Company entitled to vote, voting together as a single class. Except as otherwise provided by law, amendments to the articles of incorporation generally must be approved by a majority of the votes entitled to be cast by all outstanding shares of common stock. Our articles of incorporation do not provide for cumulative voting in the election of directors. Our directors are divided into three classes. At each annual meeting of stockholders, directors elected to succeed those directors whose terms expire are elected for a term of office to expire at the third succeeding annual meeting of stockholders after their election. The holders of our common stock are entitled to receive ratably such dividends, if any, as may be declared by our board of directors out of legally available funds; however, the current policy of our board of directors is to retain earnings, if any, for operations and growth. Upon liquidation, dissolution or winding-up, the holders of our common stock are entitled to share ratably in all assets that are legally available for distribution after payment of our liabilities. The holders of our common stock have no preemptive, subscription, redemption or conversion rights.

The foregoing description summarizes important terms of our capital stock, but is not complete. For the complete terms of our common stock, please refer to our articles of incorporation, as amended, and our amended and restated bylaws, as may be amended from time to time.

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company. Our common stock is listed on the Nasdaq Capital Market under the symbol NVIV.

Series B Pre-Funded Warrants

The following summary of certain terms and provisions of the Series B pre-funded warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Series B pre-funded warrant, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Series B pre-funded warrant for a complete description of the terms and conditions of the Series B pre-funded warrants.

Duration and Exercise Price

Each Series B pre-funded warrant offered hereby will have an initial exercise price per share equal to $0.01. The Series B pre-funded warrants will be immediately exercisable and will expire twenty years from the date of issuance, subject to earlier call rights exercisable by the Company and/or tolling, in each case under specified circumstances. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The Series B pre-funded warrants will be issued separately from the accompanying Series A warrants with Series B pre-funded warrants.

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Exercisability

The Series B pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Series B pre-funded warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days prior notice from the holder to us, the holder may increase the amount of beneficial ownership of outstanding stock after exercising the holder s Series B pre-funded warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Series B pre-funded warrants and Nevada law. Purchasers of Series B pre-funded warrants in this offering may also elect prior to the issuance of the Series B pre-funded warrants to have the initial exercise limitation set at 9.99% of our outstanding common stock.

Cashless Exercise

If, at the time a holder exercises its Series B pre-funded warrants, a registration statement registering the issuance of the shares of common stock underlying the Series B pre-funded warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Series B pre-funded warrants.

Transferability

Subject to applicable laws, a Series B pre-funded warrant may be transferred at the option of the holder upon surrender of the Series B pre-funded warrant to us together with the appropriate instruments of transfer.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the Series B pre-funded warrants. Rather, the number of shares of common stock to be issued will be rounded to the nearest whole number.

Trading Market

There is no trading market available for the Series B pre-funded warrants on any securities exchange or nationally recognized trading system. The common stock issuable upon exercise of the Series B pre-funded warrants is listed on the Nasdaq Capital Market.

Right as a Stockholder

Except as otherwise provided in the Series B pre-funded warrants or by virtue of such holder s ownership of shares of our common stock, the holders of the Series B pre-funded warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Series B pre-funded warrants. The Series B pre-funded warrants will provide that holders have the right to participate in distributions or dividends paid on our common stock.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Series B pre-funded warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the Series B pre-

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funded warrants will be entitled to receive upon exercise of the Series B pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Series B pre-funded warrants immediately prior to such fundamental transaction.

Series A warrants

The following summary of certain terms and provisions of the Series A warrants included with the shares of common stock and the Series B pre-funded warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Series A warrants, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of Series A warrant for a complete description of the terms and conditions of the Series A warrants.

Duration and Exercise Price

Each Series A warrant offered hereby will have an initial exercise price equal to $2.00 per share of common stock. The Series A warrants will be immediately exercisable and will expire five years from the date of issuance. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The Series A warrants will be issued separately from the common stock, or the Series B pre-funded warrants, as the case may be.

Exercisability

The Series A warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the Series A warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days prior notice from the holder to us, the holder may increase the amount of beneficial ownership of outstanding stock after exercising the holder s Series A warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Series A warrants and Nevada law.

Cashless Exercise

If, at the time a holder exercises its Series A warrants, a registration statement registering the issuance of the shares of common stock underlying the Series A warrants under the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Series A warrants.

Fractional Shares

No fractional shares of common stock will be issued upon the exercise of the Series A warrants. Rather, the number of shares of common stock to be issued will be rounded to the nearest whole number.

Transferability

Subject to applicable laws, a Series A warrant may be transferred at the option of the holder upon surrender of the Series A warrant to us together with the appropriate instruments of transfer.

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Exchange Listing

We do not intend to list the Series A warrants on any securities exchange or nationally recognized trading system. The common stock issuable upon exercise of the Series A warrants is listed on the Nasdaq Capital Market.

Right as a Stockholder

Except as otherwise provided in the Series A warrants or by virtue of such holder s ownership of shares of our common stock, the holders of the Series A warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their Series A warrants.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Series A warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the Series A warrants will be entitled to receive upon exercise of the Series A warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Series A warrants immediately prior to such fundamental transaction. In addition, in the event of a fundamental transaction which is approved by our Board, the holders of the Series A warrants have the right to require us or a successor entity to redeem the Series A warrant for cash in the amount of the Black-Scholes value of the unexercised portion of the Series A warrant on the date of the consummation of the fundamental transaction. In the event of a fundamental transaction which is not approved by our Board, the holders of the Series A warrants have the right to require us or a successor entity to redeem the Series A warrant for the consideration paid in the fundamental transaction in the amount of the Black Scholes value of the unexercised portion of the Series A warrant on the date of the consummation of the fundamental transaction.

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MATERIAL U.S. FEDERAL TAX CONSIDERATIONS FOR HOLDERS OF OUR COMMON STOCK, SERIES B PRE-FUNDED WARRANTS AND SERIES A WARRANTS

The following discussion describes the material U.S. federal income tax consequences of the acquisition, ownership and disposition of our common stock, Series B pre-funded warrants and Series A warrants acquired in this offering. This discussion is based on the current provisions of the Internal Revenue Code of 1986, as amended (referred to as the Code), existing and proposed U.S. Treasury regulations promulgated thereunder, and administrative rulings and court decisions in effect as of the date hereof, all of which are subject to change at any time, possibly with retroactive effect. No ruling has been or will be sought from the Internal Revenue Service, or IRS, with respect to the matters discussed below, and there can be no assurance the IRS will not take a contrary position regarding the tax consequences of the acquisition, ownership or disposition of our common stock, Series B pre-funded warrants or Series A warrants, or that any such contrary position would not be sustained by a court.

We assume in this discussion that the shares of our common stock, Series B pre-funded warrants and Series A warrants will be held as capital assets (generally, property held for investment). This discussion does not address all aspects of U.S. federal income taxes, does not discuss the potential application of the Medicare contribution tax, the alternative minimum tax and does not deal with state or local taxes, U.S. federal gift and estate tax laws, except as specifically provided below with respect to non-U.S. holders, or any non-U.S. tax consequences that may be relevant to holders in light of their particular circumstances. This discussion also does not address the special tax rules applicable to particular holders, such as:

- financial institutions;
- brokers or dealers in securities;
- tax-exempt organizations;
- pension plans;
- regulated investment companies;
- owners that hold our common stock, Series B pre-funded warrants or Series A warrants as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- insurance companies;

- controlled foreign corporations, passive foreign investment companies, or corporations that accumulate earnings to avoid U.S. federal income tax; and

- certain U.S. expatriates.

In addition, this discussion does not address the tax treatment of partnerships or other pass-through entities or persons who hold our common stock, Series B pre-funded warrants or Series A warrants through partnerships or other entities which are pass-through entities for U.S. federal income tax purposes. A partner in a partnership or other pass-through entity that will hold our common stock, Series B pre-funded warrants or Series A warrants should consult his, her or its own tax advisor regarding the tax consequences of the ownership and disposition of our common stock, Series B pre-funded warrants or Series A warrants through a partnership or other pass-through entity, as applicable.

The discussion of U.S. federal income tax considerations is for information purposes only and is not tax advice. Prospective investors should consult their own tax advisors regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of acquiring, holding and disposing of our common stock, Series B pre-funded warrants and Series A warrants.

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For the purposes of this discussion, a U.S. Holder means a beneficial owner of our common stock, Series B pre-funded warrants or Series A warrants that is for U.S. federal income tax purposes (a) an individual citizen or resident of the United States, (b) a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes), created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate the income of which is subject to U.S. federal income taxation regardless of its source, or (d) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons (within the meaning of Section 7701(a)(30) of the Code) have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person. A Non-U.S. Holder is, for U.S. federal income tax purposes, a beneficial owner of common stock, Series B pre-funded warrants or Series A warrants that is not a U.S. Holder or a partnership for U.S. federal income tax purposes.

Tax Cuts and Jobs Act

Under tax legislation signed into law in December 2017 commonly known as the Tax Cuts and Jobs Act of 2017, U.S. Holders that use an accrual method of accounting for tax purposes and have certain financial statements generally will be required to include certain amounts in income no later than the time such amounts are taken into account as revenue in such financial statements. The application of this rule thus may require the accrual of income earlier than would be the case under the general tax rules described below, although the precise application of this rule is unclear at this time. This rule generally will be effective for taxable years beginning after December 31, 2017. U.S. Holders that use an accrual method of accounting should consult with their tax advisors regarding the potential applicability of this legislation to their particular situation.

Allocation of Purchase Price to Common Stock, Pre-funded Warrants and Warrants

For U.S. federal income tax purposes, a holder s acquisition of the warrants and common stock or prefunded warrants, as applicable, will be treated as the acquisition of an investment unit consisting of one share of common stock or one pre-funded warrant, as applicable, and a warrant to acquire one share of our common stock, subject to adjustment. The purchase price for each investment unit will be allocated between these two components in proportion to their relative fair market values at the time the unit is purchased by the holder. This allocation of the purchase price for each unit will establish the holder s initial tax basis for U.S. federal income tax purposes in the common stock or pre-funded warrant, as applicable, and the warrant included in each unit. The separation of the share of common stock or pre-funded warrant, as applicable, and the warrant included in each unit should not be a taxable event for U.S. federal income tax purposes. Each holder should consult his, her or its own tax advisor regarding the allocation of the purchase price for a unit.

Treatment of Series B Pre-Funded Warrants

Although it is not entirely free from doubt, a Series B pre-funded warrant should be treated as a share of our common stock for U.S. federal income tax purposes and a holder of Series B pre-funded warrants should generally be taxed in the same manner as a holder of common stock as described below. Accordingly, upon exercise, the holding period of a Series B pre-funded warrant should carry over to the share of common stock received. Similarly, the tax basis of the Series B pre-funded warrant should carry over to the share of common stock received upon exercise increased by the exercise price of $0.01. Each holder should consult his, her or its own tax advisor regarding the risks associated with the acquisition of a unit pursuant to this offering (including potential alternative characterizations).

The balance of this discussion generally assumes that the characterization described above is respected for U.S. federal income tax purposes.

Tax Considerations Applicable to U.S. Holders

Exercise and Expiration of Series A Warrants

In general, a U.S. Holder will not recognize gain or loss for U.S. federal income tax purposes upon exercise of a warrant. The U.S. Holder will take a tax basis in the shares acquired on the exercise of a Series A warrant equal to the exercise price of the Series A warrant, increased by the U.S. Holder s adjusted tax basis in the Series A warrant exercised (as determined pursuant to the rules discussed above). The U.S. Holder s holding period in the shares of our common stock acquired on exercise of the Series A warrant will begin on the date of exercise of the Series A warrant, and will not include any period for which the U.S. Holder held the Series A warrant.

In certain limited circumstances, a U.S. Holder may be permitted to undertake a cashless exercise of Series A warrants into our common stock. The U.S. federal income tax treatment of a cashless exercise of Series A warrants into our common stock is unclear, and the tax consequences of a cashless exercise could differ from the consequences upon the exercise of a Series A warrant described in the preceding paragraph. U.S. Holders should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise of Series A warrants.

The lapse or expiration of a Series A warrant will be treated as if the U.S. Holder sold or exchanged the Series A warrant and recognized a capital loss equal to the U.S. Holder s tax basis in the Series A warrant. The deductibility of capital losses is subject to limitations.

Certain Adjustments to and Distributions on the Series A Warrants

Under Section 305 of the Code, an adjustment to the number of shares of common stock issued on the exercise of the Series A warrants, or an adjustment to the exercise price of the Series A warrants, may be treated as a constructive distribution to a U.S. Holder of the Series A warrants if, and to the extent that, such adjustment has the

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effect of increasing such U.S. Holder s proportionate interest in our earnings and profits or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). In addition, if we were to make a distribution in cash or other property with respect to our common stock after the issuance of the Series A warrants, then we may, in certain circumstances, make a corresponding distribution to a Series A warrant holder. The taxation of a distribution received with respect to a Series A warrant is unclear. It is possible such a distribution would be treated as a distribution (or constructive distribution), although other treatments are possible. For more information regarding the tax considerations related to distributions, see the discussion below regarding Distributions. U.S. Holders should consult their tax advisors regarding the proper treatment of any adjustments to and adjustments on the Series A warrants.

Distributions

As discussed above, 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. In the event that we do make distributions on our common stock or Series B pre-funded warrants to a U.S. Holder, those distributions generally will constitute dividends for U.S. tax purposes to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Distributions in excess of our current and accumulated earnings and profits will constitute a return of capital that is applied against and reduces, but not below zero, a U.S. Holder s adjusted tax basis in our common stock or Series B pre-funded warrant, as applicable. Any remaining excess will be treated as gain realized on the sale or exchange of our common stock or Series B pre-funded warrant as described below under the section titled Gain on Disposition of Our Common Stock, Series B Pre-Funded Warrants or Series A Warrants.

Gain on Disposition of Our Common Stock, Series B Pre-Funded Warrants or Series A Warrants

Upon a sale or other taxable disposition of our common stock, Series B pre-funded warrants or Series A warrants, a U.S. Holder generally will recognize capital gain or loss in an amount equal to the difference between the amount realized and the U.S. Holder s adjusted tax basis in the common stock, Series B pre-funded warrants or Series A warrants. Capital gain or loss will constitute long-term capital gain or loss if the U.S. Holder s holding period for the common stock, Series B pre-funded warrant or Series A warrant exceeds one year. The deductibility of capital losses is subject to certain limitations. U.S. Holders who recognize losses with respect to a disposition of our common stock, Series B pre-funded warrants or Series A warrants should consult their own tax advisors regarding the tax treatment of such losses.

Information Reporting and Backup Withholding

Information reporting requirements generally will apply to payments of dividends (including constructive dividends) on the common stock, Series B pre-funded warrants and Series A warrants and to the proceeds of a sale or other disposition of common stock, Series A warrants and Series B pre-funded warrants paid by us to a U.S. Holder unless such U.S. Holder is an exempt recipient, such as a corporation. Backup withholding will apply to those payments if the U.S. Holder fails to provide the holder s taxpayer identification number, or certification of exempt status, or if the holder otherwise fails to comply with applicable requirements to establish an exemption. Backup withholding is not an additional tax. Rather, any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against the U.S. Holder s U.S. federal income tax liability provided the required information is timely furnished to the IRS.

Tax Considerations Applicable to Non-U.S. Holders

Exercise and Expiration of Series A Warrants

In general, a Non-U.S. Holder will not be subject to U.S. federal income tax on the exercise of the Series A warrants into shares of common stock. The U.S. federal income tax treatment of a cashless exercise of Series A warrants into our common stock is unclear. A Non-U.S. Holder should consult his, her, or its own tax advisor regarding the U.S. federal income tax consequences of a cashless exercise of Series A warrants.

The expiration of a Series A warrant will be treated as if the Non-U.S. Holder sold or exchanged the Series A warrant and recognized a capital loss equal to the Non-U.S. Holder s tax basis in the Series A warrant. However, a Non-U.S. Holder will not be able to utilize a loss recognized upon expiration of a Series A warrant against the Non-U.S. Holder s U.S. federal income tax liability unless the loss is effectively connected with the Non-U.S. Holder s conduct of a trade or business within the United States (and, if an income tax treaty applies, is attributable to a

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permanent establishment or fixed base in the United States) or is treated as a U.S.-source loss and the Non-U.S. Holder is present 183 days or more in the taxable year of disposition and certain other conditions are met.

Certain Adjustments to and Distributions on the Series A Warrants

As described under U.S. Holders Certain Adjustments to the Series A Warrants, an adjustment to the Series A warrants could result in a constructive distribution to a Non-U.S. Holder, which would be treated as described under Distributions below, and the tax treatment of a distribution on a warrant is unclear. Any resulting withholding tax attributable to deemed dividends would be collected from other amounts payable or distributable to the Non-U.S. Holder. Non-U.S. Holders should consult their tax advisors regarding the proper treatment of any adjustments to and distributions on the Series A warrants.

Distributions

As discussed above, 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. In the event that we do make distributions on our common stock or Series B pre-funded warrants to a Non-U.S. Holder, those distributions generally will constitute dividends for U.S. federal income tax purposes as described in U.S. Holders Distributions.

Any distribution (including constructive distributions) on our common stock or Series B pre-funded warrants that is treated as a dividend paid to a Non-U.S. Holder that is not effectively connected with the holder s conduct of a trade or business in the United States will generally be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and the Non-U.S. Holder s country of residence. To obtain a reduced rate of withholding under a treaty, a Non-U.S. Holder generally will be required to provide the applicable withholding agent with a properly executed IRS Form W-8BEN, IRS Form W-8BEN-E or other appropriate form, certifying the Non-U.S. Holder s entitlement to benefits under that treaty. Such form must be provided prior to the payment of dividends and must be updated periodically. If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the holder s behalf, the holder will be required to provide appropriate documentation to such agent. The holder s agent may then be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. withholding tax under an income tax treaty, you should consult with your own tax advisor to determine if you are able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

We generally are not required to withhold tax on dividends paid (or constructive dividends deemed paid) to a Non-U.S. Holder that are effectively connected with the holder s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base that the holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us (or, if stock is held through a financial institution or other agent, to the applicable withholding agent). In general, such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates applicable to U.S. persons. A corporate Non-U.S. Holder receiving effectively connected dividends may also be subject to an additional branch profits tax, which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder s effectively connected earnings and profits, subject to certain adjustments.

See also the sections below titled Information Reporting and Backup Withholding and Foreign Accounts for additional withholding rules that may apply to dividends paid to certain foreign financial institutions or non-financial foreign entities.

Gain on Disposition of Our Common Stock, Series B Pre-Funded Warrants or Series A Warrants

Subject to the discussions below under the sections titled Information Reporting and Backup Withholding and Foreign Accounts, a Non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax with respect to gain realized on a sale or other disposition of our common stock, Series B pre-funded warrant or Series A warrants unless

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- the gain is effectively connected with the Non-U.S. Holder s conduct of a trade or business in the United States, and if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by the Non-U.S. Holder in the United States; in these cases, the Non-U.S. Holder will be taxed on a net income basis at the regular graduated rates and in the manner applicable to U.S. persons, and if the Non-U.S. Holder is a corporation, an additional branch profits tax at a rate of 30%, or a lower rate as may be specified by an applicable income tax treaty, may also apply;

- the Non-U.S. Holder is a nonresident alien present in the United States for 183 days or more in the taxable year of the disposition and certain other requirements are met, in which case the Non-U.S. Holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder s country of residence) on the net gain derived from the disposition, which may be offset by certain U.S.-source capital losses of the Non-U.S. Holder, if any; or

- we are, or have been at any time during the five-year period preceding such disposition (or the Non-U.S. Holder s holding period of the common stock, Series B pre-funded warrants or Series A warrants, if shorter), a U.S. real property holding corporation, unless our common stock is regularly traded on an established securities market and the Non-U.S. Holder held no more than 5% of our outstanding common stock, directly or indirectly, during the shorter of the five-year period ending on the date of the disposition or the period that the Non-U.S. Holder held our common stock. Special rules may apply to the determination of the 5% threshold in the case of a holder of a Series B pre-funded warrant or Series A warrant. Non-U.S. Holders are urged to consult their own tax advisors regarding the effect of holding our Series B pre-funded warrants or Series A warrants on the calculation of such 5% threshold. Generally, a corporation is a U.S. real property holding corporation if the fair market value of its U.S. real property interests (as defined in the Code and applicable regulations) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we believe that we are not currently, and we do not anticipate becoming, a U.S. real property holding corporation for U.S. federal income tax purposes. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

See the sections titled Information Reporting and Backup Withholding and Foreign Accounts below for additional information regarding withholding rules that may apply to proceeds of a disposition of our common stock, Series B pre-funded warrants or Series A warrants paid to foreign financial institutions or non-financial foreign entities.

Federal Estate Tax

Common stock or Series B pre-funded warrants owned or treated as owned by an individual who is a Non-U.S. Holder (as specially defined for U.S. federal estate tax purposes) at the time of death will be included in the individual s gross estate for U.S. federal estate tax purposes and, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax or other treaty provides otherwise. The foregoing may also apply to Series A warrants.

Information Reporting and Backup Withholding

We must report annually to the IRS and to each Non-U.S. Holder the gross amount of the distributions (including constructive distributions) on our common stock, Series B pre-funded warrants or Series A warrants paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. Holders may have to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate, currently 24%, with respect to dividends (including constructive dividends) on our common stock Series B pre-funded warrants, or Series A warrants. Generally, a holder will comply with such procedures if it provides a properly executed IRS Form W-8BEN (or other applicable Form W-8) or otherwise meets documentary evidence requirements for establishing that it is a Non-U.S. Holder, or otherwise establishes an exemption. Dividends paid to Non-U.S. Holders subject to withholding of U.S. federal income tax, as described above under the heading Dividends, will generally be exempt from U.S. backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock, Series B pre-funded warrants or Series A warrants by a Non-U.S. Holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a Non-U.S. Holder and satisfies certain

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other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. Holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the Non-U.S. Holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a Non-U.S. Holder can be refunded or credited against the Non-U.S. Holder s U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

Foreign Accounts

The Foreign Account Tax Compliance Act, or FATCA, generally imposes a 30% withholding tax on dividends on, and gross proceeds from the sale or other disposition of, common stock, Series B pre-funded warrants and Series A warrants if paid to a non-U.S. entity unless (i) if the non-U.S. entity is a foreign financial institution, the non-U.S. entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the non-U.S. entity is not a foreign financial institution, the non-U.S. entity identifies certain of its U.S. investors, if any, or (iii) the non-U.S. entity is otherwise exempt under FATCA.

Withholding under FATCA generally (1) applies to payments of dividends on our common stock, Series B pre-funded warrants and Series A warrants and (2) will apply to payments of gross proceeds from a sale or other disposition of our common stock, Series B pre-funded warrants and Series A warrants made after December 31, 2018. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this section. Under certain circumstances, a holder may be eligible for refunds or credits of the tax. Holders should consult their own tax advisors regarding the possible implications of FATCA on their investment in our common stock, Series B pre-funded warrants or Series A warrants.

The preceding discussion of material U.S. federal tax considerations is for information only. It is not tax advice. Prospective investors should consult their own tax advisors regarding the particular U.S. federal, state, local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, Series B pre-funded warrants or Series A warrants, including the consequences of any proposed changes in applicable laws.

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UNDERWRITING

We have entered into an underwriting agreement with Ladenburg Thalmann & Co. Inc., as the representative of the sole underwriter (the representative) named below and the sole book-running manager of this offering. Subject to the terms and conditions of the underwriting agreement, the underwriter has agreed to purchase the number of our securities set forth opposite its name below.

Underwriter	SHARES	SERIES B PRE-FUNDED WARRANTS	SERIES A WARRANTS
Ladenburg Thalmann & Co. Inc.	388,403	6,242,811	6,631,214

A copy of the underwriting agreement has been filed as an exhibit to the registration statement of which this prospectus is part.

We have been advised by the underwriter that it proposes to offer the shares, the Series B pre-funded warrants and the Series A warrants directly to the public at the public offering prices set forth on the cover page of this prospectus. Any securities sold by the underwriter to securities dealers will be sold at the public offering price less a selling concession not in excess of $0.09552 per share and $0.00048 per Series A Warrant.

The underwriting agreement provides that the underwriter s obligation to purchase the securities we are offering is subject to conditions contained in the underwriting agreement.

No action has been taken by us or the underwriter that would permit a public offering of the shares and warrants in any jurisdiction where action for that purpose is required. None of our securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sales of any of the securities offering hereby be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of securities and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy the shares and warrants in any jurisdiction where that would not be permitted or legal.

The underwriter has advised us that it does not intend to confirm sales to any accounts over which it exercises discretionary authority.

Underwriting Discount and Expenses

The following table summarizes the underwriting discount and commission to be paid to the underwriter by us.

	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 to be paid to the underwriter by us (8.0%)	$ 0.16	$ 0.16	$ 1,056,000
Proceeds to us (before expenses)	$ 1.84	$ 1.83	$ 12,144,000

We estimate the total expenses payable by us for this offering to be approximately $1.5 million, which amount includes (i) the underwriting discount of $1.1 million ($1.2 million if the underwriter s over-allotment option is exercised in full), (ii) reimbursement of the accountable expenses of the representative of up to $0.1 million, including the legal fees of the

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representative being paid by us, $15,000 of which has been paid prior to the date hereof and is subject to FINRA Rule 5110(f)(2)(C), and (iii) other estimated company expenses of approximately $0.3 million, which includes legal, accounting, printing costs and various fees associated with the registration and listing of our shares. In no event will the aggregated expenses of the representative reimbursed exceed $100,000.

The securities we are offering are being offered by the underwriter subject to certain conditions specified in the underwriting agreement.

Over-allotment Option

We have granted to the underwriter an option, exercisable not later than 45 days after the date of this prospectus, to purchase up to 989,997 additional shares of common stock and/or up to 989,997 additional Series A warrants to purchase shares of common stock. Any shares and Series A warrants so purchased shall be sold at a price per share equal to the public offering price, less the underwriting discount. The underwriter may exercise the option solely to cover over-allotments, if any, made in connection with this offering. If any additional shares of common stock and/or Series A warrants are purchased pursuant to the over-allotment option, the underwriter will offer these shares of common stock and/or Series A warrants on the same terms as those on which the other securities are being offered hereby.

Determination of Offering Price

The public offering price of the securities offered by this prospectus was determined by negotiation between us and the underwriter. Among the factors considered in determining the public offering price of the shares were:

- our history and our prospects;
- the industry in which we operate;
- our past and present operating results
- the previous experience of our executive officers; and
- the general condition of the securities markets at the time of this offering

The offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the shares of common stock and Series A warrants. That price is subject to change as a result of market conditions and other factors, and we cannot assure you that the shares of common stock and Series A warrants can be resold at or above the public offering price.

Lock-up Agreements

Our officers and directors have agreed with the representative to be subject to a lock-up period of 90 days following the date of this prospectus. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. We have also agreed, in the underwriting agreement, to similar lock-up restrictions on the issuance and sale of our securities for 90 days following the closing of this offering, although we will be permitted to issue stock options or stock awards to directors, officers and employees under our existing plans. The lock-up period is subject to an additional extension to accommodate for our reports of financial results or material news releases. The representative may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements.

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Other Relationships

Upon completion of this offering, we have granted the underwriter a right of first refusal to act as lead or co-lead underwriter or placement agent in connection with any subsequent public or private offering of equity securities or other capital markets financing by us. This right of first refusal extends for twelve months from the effective date of this registration statement. The terms of any such engagement of the underwriter will be determined by separate agreement.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company.

Stabilization, Short Positions and Penalty Bids

The underwriter may engage in syndicate covering transactions, stabilizing transactions and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of our common stock:

- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriter is concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specific maximum.

- Penalty bids permit the underwriter to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These syndicate covering transactions, stabilizing transactions and penalty bids may have the effect of raising or maintaining the market prices of our securities or preventing or retarding a decline in the market prices of our securities. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriter make any representation or prediction as to

the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on The Nasdaq Capital Market, in the over-the-counter market or on any other trading market and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriter also may engage in passive market making transactions in our common stock in accordance with Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker s bid, that bid must then be lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

Neither we nor the underwriter make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the prices of our securities. In addition, neither we nor the underwriter make any representation that the underwriter will engage in these transactions or that any transactions, once commenced, will not be discontinued without notice.

Indemnification

We have agreed to indemnify the underwriter and selected dealers against certain liabilities, including certain liabilities arising under the Securities Act, or to contribute to payments that the underwriter or selected dealers may be required to make for these liabilities.

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LEGAL MATTERS

The validity of the common stock offered by this prospectus supplement and the accompanying prospectus will be passed upon for us by Ballard Spahr LLP, Las Vegas, Nevada, and certain other legal matters will be passed upon for us by Wilmer Cutler Pickering Hale and Dorr LLP, Boston, Massachusetts. Ellenoff Grossman & Schole LLP, New York, New York, has acted as counsel for the underwriter in connection with certain legal matters related to this offering.

EXPERTS

The consolidated financial statements of InVivo Therapeutics Holdings Corp. and Subsidiary as of December 31, 2017 and 2016 and for each of the years in the three-year period ended December 31, 2017 and the effectiveness of internal control over financial reporting as of December 31, 2017 incorporated in this Prospectus by reference from the InVivo Therapeutics Holdings Corp. Annual Report on Form 10-K for the year ended December 31, 2017 have been audited by RSM US LLP, an independent registered public accounting firm, as stated in their report thereon (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the Company s ability to continue as a going concern) incorporated herein by reference, and have been incorporated in this Prospectus and Registration Statement in reliance upon such reports and upon the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We are subject to the informational requirements of the Exchange Act and in accordance therewith file annual, quarterly and current reports, proxy statements and other information with the SEC. Such reports, proxy statements and other information can be read and copied at the SEC s public reference facilities at 100 F Street, N.E., Washington, D.C. 20549, at prescribed rates. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. In addition, the SEC maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the SEC s website is www.sec.gov.

We make available free of charge on or through our website at www.invivotherapeutics.com, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with or otherwise furnish it to the SEC.

We have filed with the SEC a registration statement under the Securities Act relating to the offering of these securities. The registration statement, including the attached exhibits, contains additional relevant information about us and the securities. This prospectus does not contain all of the information set forth in the registration statement. You can obtain a copy of the registration statement, at prescribed rates, from the SEC at the address listed above, or for free at www.sec.gov. The registration statement and the documents referred to below under Incorporation of Certain Information By Reference are also available on our website, www.invivotherapeutics.com.

We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this prospectus.

INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference the information we have filed with it, which means that we can disclose important information to you by referring you to those documents. The information we incorporate by reference is an important part of this prospectus, and later information that we file with the SEC will automatically update and supersede this information. We specifically are incorporating by reference the following documents filed with the SEC (excluding those portions that are furnished and not deemed filed):

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- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on March 12, 2018;

- Our Definitive Proxy Statement on Schedule 14A, filed with the SEC on April 27, 2018;

- Our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2018, filed with the SEC on May 7, 2018;

- Our Current Reports on Form 8-K, filed with the SEC on January 3, 2018, January 23, 2018, January 26, 2018, January 29, 2018, February 5, 2018, April 9, 2018, April 16 2018, May 14, 2018, June 1, 2018 and June 19, 2018; and

- The description of our common stock contained in our Registration Statement on Form 8-A filed on April 15, 2015, including any amendments or reports filed for the purpose of updating such description.

You should rely only on the information incorporated by reference or provided in this prospectus. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus is accurate as of any date other than the date of this prospectus or the date of the documents incorporated by reference in this prospectus.

We will provide without charge to each person, including any beneficial owner, to whom a copy of this prospectus is delivered, upon written or oral request, a copy of any or all of the information that has been incorporated by reference in this prospectus but not delivered with this prospectus (other than an exhibit to these filings, unless we have specifically incorporated that exhibit by reference in this prospectus). Any such request should be addressed to us at:

InVivo Therapeutics Holdings, Inc.

Attn: Secretary

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

You may also access the documents incorporated by reference in this prospectus through our website at www.invivotherapeutics.com. Except for the specific incorporated documents listed above, no information available on or through our website shall be deemed to be incorporated in

this prospectus or the registration statement of which it forms a part.

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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

Prospectus

LADENBURG THALMANN

June 20, 2018