

INVIVO THERAPEUTICS HOLDINGS CORP.  
Form 424B5  
July 29, 2015

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Filed Pursuant to Rule 424(b)(5)  
Registration No. 333-188573

**PROSPECTUS SUPPLEMENT**  
(To the Prospectus dated May 22, 2013)

**\$50,000,000**

## **INVIVO THERAPEUTICS HOLDINGS CORP.**

### **Common Stock**

We have entered into a sales agreement with Cowen and Company, LLC, or Cowen, relating to shares of our common stock, \$0.00001 par value per share, offered by this prospectus supplement and the accompanying prospectus. In accordance with the terms of the sales agreement, we may offer and sell shares of our common stock having an aggregate offering price of up to \$50,000,000 from time to time through Cowen, acting as our agent.

Our common stock is listed on The NASDAQ Capital Market under the symbol "NVIV." The last reported sale price of our common stock on July 22, 2015 was \$16.82 per share.

Upon our delivery of a placement notice and subject to the terms and conditions of the sales agreement, Cowen may sell the common stock by methods deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act, including sales made directly on The NASDAQ Capital Market, on any other existing trading market for the common stock or to or through a market maker. In addition, with our prior written approval, Cowen may also sell the common stock by any other method permitted by law, including in negotiated transactions. Cowen will act as sales agent using its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of The NASDAQ Stock Market.

We will pay Cowen a commission equal to 3.0% of the gross sales price per share sold through Cowen acting as agent pursuant to the sales agreement. In connection with the sale of the common stock on our behalf, Cowen will be deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of Cowen will be deemed to be underwriting commissions or discounts. We have also agreed to provide indemnification and contribution to Cowen with respect to certain liabilities, including liabilities under the Securities Act or the Securities Exchange Act of 1934, as amended, or the Exchange Act. See "Plan of Distribution" on S-25 of this prospectus supplement.

**Investing in our common stock involves risks, including those described in the "Risk Factors" section beginning on page S-5 of this prospectus supplement and the section captioned "Item 1A Risk Factors" in our most recently filed Annual Report on Form 10-K or Quarterly Report on Form 10-Q, which is incorporated by reference into this prospectus supplement and the accompanying prospectus.**

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

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## **Cowen and Company**

**July 29, 2015**

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**ABOUT THIS PROSPECTUS SUPPLEMENT**

This document is in two parts. The first part is the prospectus supplement, including the documents incorporated by reference, which describes the specific terms of this offering. The second part, the accompanying prospectus, including documents incorporated by reference, provides more general information. Generally, when we refer to this prospectus supplement, we are referring to both parts of this document combined. Before you invest, you should carefully read this prospectus supplement, the accompanying prospectus, all information incorporated by reference herein and therein, as well as the additional information described under "Where You Can Find Additional Information" on page S-27 of this prospectus supplement. These documents contain information that you should consider when making your investment decision. This prospectus supplement may add, update or change information contained in the accompanying prospectus. To the extent that any statement that we make in this prospectus supplement is inconsistent with statements made in the accompanying prospectus or any documents incorporated by reference therein, the statements made in this prospectus supplement will be deemed to modify or supersede those made in the accompanying prospectus and such documents incorporated by reference therein.

You should rely only on the information contained or incorporated by reference in this prospectus supplement, the accompanying prospectus and in any free writing prospectuses that we may provide to you in connection with this offering. We have not, and Cowen has not, authorized any other person to provide you with any information that is different. If anyone provides you with different or inconsistent information, you should not rely on it. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where the offers or sales are permitted. The distribution of this prospectus supplement and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement outside the United States. This prospectus supplement does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

Unless the context indicates otherwise, as used in this prospectus supplement, the terms "InVivo," "the Company," "our company," "we," "us" and "our" refer to InVivo Therapeutics Holdings Corp. and its subsidiaries. This prospectus supplement, the accompanying prospectus and the other documents incorporated by reference contain references to our trademarks, service marks and trade names as well as third-party trademarks. Solely for convenience, trademarks and trade names may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and trade names.

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**PROSPECTUS SUPPLEMENT SUMMARY**

*This summary highlights selected information about us, this offering and information appearing elsewhere in this prospectus supplement, in the accompanying prospectus and in the documents we incorporated by reference. This summary is not complete and does not contain all the information that you should consider before deciding whether to invest in our common stock pursuant to this prospectus supplement and the accompanying prospectus. Before making an investment decision, to fully understand this offering and its consequences to you, you should carefully read the entire prospectus supplement and the accompanying prospectus, including the "Risk Factors" beginning on page S-5 of this prospectus supplement, the financial statements and related notes and the other information that we incorporate by reference herein, including our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q we file from time to time.*

**InVivo Therapeutics Holdings Corp.**

**Overview**

We are a research and clinical-stage biomaterials and biotechnology company with a focus on treatment of spinal cord injuries. Our proprietary technologies incorporate intellectual property licensed under an exclusive, world-wide license from Boston Children's Hospital and the Massachusetts Institute of Technology, and intellectual property that has been developed internally, including in collaboration with our advisors and partners. We intend to leverage our platform technology to develop our novel Neuro-Spinal Scaffold, an investigational bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord contusion and is intended to treat acute spinal cord injury, or SCI. We believe our Neuro-Spinal Scaffold will be the foundation of effective therapy for both acute and chronic SCI, and we are continually evaluating other technologies and therapeutics that may be complementary and that offer the potential to bring us closer to our goal of redefining the life of the SCI patient.

Our clinical program is intended to address the lack of successful treatments for SCIs. The current management of acute SCI is a surgical approach consisting of spine stabilization and a decompression procedure of uncertain value. Our mission is to redefine the life of the SCI patient. We are developing treatment options intended to provide meaningful improvement in patient outcomes following SCI. Our approach to treating SCIs is based on our investigational Neuro-Spinal Scaffold, which we believe is the only SCI therapy in development focused solely on treating SCI directly at the epicenter of the injury.

We believe the market opportunity for our Neuro-Spinal Scaffold and our technology is significant. It is estimated that approximately 276,000 people are currently living in the United States with paralysis due to spinal cord injury, and approximately 12,500 individuals in the United States will become fully or partially paralyzed each year. The regulatory approval pathway for a Humanitarian Device Exemption (HDE) we are initially pursuing would, if FDA approval is granted, cover a potential population of up to 4,000 SCI patients. This population includes patients afflicted with complete spinal cord injury, *i.e.*, paraplegia or tetraplegia, and excludes gunshot or other penetrating wounds). SCI can lead to permanent paralysis, sensory impairment, and autonomic, bowel, bladder, and sexual dysfunction. Future products, which may include use of stem cells or drug ingredients combined with the scaffold, may enable the treatment of a broader population, which would require separate regulatory approval. The financial impact of spinal cord injuries, as reported by the National Spinal Cord Injury Statistical Center at the University of Alabama, or NSCISC, is substantial. These costs place a tremendous financial burden on families, insurance providers, and government

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agencies. Moreover, despite such a significant financial investment, the patient often remains disabled for life because current medical interventions address only the symptoms of SCI rather than the underlying neurological cause. We believe our approach could represent an important advance in the treatment of SCIs.

Our leading product is our Neuro-Spinal Scaffold, an investigational bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord contusion. The Neuro-Spinal Scaffold is surgically implanted at the epicenter of the wound and acts as a physical substrate for nerve sprouting. Appositional healing to spare spinal cord tissue, decrease post-traumatic cyst formation and decreased spinal cord tissue pressure have been demonstrated in preclinical models of spinal cord contusion injury.

Our Neuro-Spinal Scaffold is currently being studied in an early feasibility, five subject pilot study under our approved IDE application for the treatment of complete traumatic acute spinal cord injury. The FDA approved the study which is intended to capture safety and feasibility of the Neuro-Spinal Scaffold for the treatment of complete functional spinal cord injury, as well as to gather preliminary evidence of the clinical effectiveness of the Neuro-Spinal Scaffold. We anticipate full enrollment of five patients in the pilot study in 2015. If our pilot study is successful, we then expect to conduct a pivotal study to show safety and probable benefit in order to obtain FDA approval to commence commercialization under a HDE. However, even if we are able to obtain FDA approval of our Neuro-Spinal Scaffold, because the Neuro-Spinal Scaffold is new, unproven technology, we will have to demonstrate the clinical utility of the product and gain acceptance from physicians and obtain third-party reimbursement for our product and there can be no assurance that we will be able to do so. For major markets outside the United States, we would be required to seek regulatory approvals in those markets after the clinical studies or trials are conducted in the United States.

**Corporate Information**

InVivo Therapeutics Corporation was incorporated on November 28, 2005 under the laws of the State of Delaware and on October 26, 2010 completed a reverse merger transaction with and became a wholly-owned subsidiary of InVivo Therapeutics Holdings Corp., a company incorporated under the laws of the State of Nevada.

Our principal executive offices are located at One Kendall Square, Suite B14402, Cambridge, Massachusetts 02139. Our telephone number is (617) 863-5500. Our worldwide web address is [www.invivotherapeutics.com](http://www.invivotherapeutics.com). Information on our website is not incorporated by reference into this prospectus supplement or the accompanying prospectus and should not be considered a part of this prospectus supplement or the accompanying prospectus.

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**THE OFFERING**

Common stock offered by us	Shares of our common stock having an aggregate offering price of up to \$50,000,000.
Manner of offering	"At the market offering" that may be made from time to time through our sales agent, Cowen and Company, LLC. Please see "Plan of Distribution" on page S-25.
Use of proceeds	We plan to use the net proceeds from this offering for general corporate purposes and working capital. Please see "Use of Proceeds" on page S-22.
Risk factors	See "Risk Factors" beginning on page S-5 of this prospectus supplement and the other information included in, or incorporated by reference into, this prospectus supplement for a discussion of factors that you should carefully consider before investing in our securities.
NASDAQ Capital Market symbol	NVIV

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**RISK FACTORS**

*Investors should carefully consider the risks described below and in the filings incorporated by reference before deciding whether to invest in our securities. We expect to update the risk factors from time to time in the periodic and current reports that we file with the SEC after the date of this prospectus supplement. These updated risk factors will be incorporated by reference in this prospectus supplement and the accompanying prospectus. The risks described below and those described in our filings incorporated by reference are not the only ones we face. If any of the following risks actually occurs, our business, financial condition or results of operations could be adversely affected. In such case, the trading price of our common stock could decline and you could lose all or part of your investment. Our actual results could differ materially from those anticipated in the forward-looking statements made throughout this prospectus supplement and in the documents incorporated by reference as a result of different factors, including the risks we face described below and those described in the filings incorporated by reference.*

**Risks Related to Our Business**

*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 \$18.3 million for the year ended December 31, 2014, and \$38.7 million for the year ended December 31, 2013. As of March 31, 2015, we had an accumulated deficit of \$116.1 million. 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.

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. 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. Our lead product candidate, Neuro-Spinal Scaffold, is currently being studied in a pilot study and, as a result, we expect that it will 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 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 payors 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 our pilot study and if successful, prepare for a pivotal study of Neuro-Spinal Scaffold;
- § continue the research and development of our 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



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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 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.

***We will need additional funding in the future. 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 to increase in connection with our ongoing activities, particularly as we conduct our clinical studies of, and seek regulatory approval for, our Neuro-Spinal Scaffold. In addition, if we obtain regulatory approval for any of our 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.

As of March 31, 2015, our consolidated cash balance was approximately \$24.5 million. We believe our current cash and cash equivalents are adequate to fund our operations into the fourth quarter of 2016. Our future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

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the scope, progress, results and costs of preclinical development, laboratory testing and clinical studies for our Neuro-Spinal Scaffold and any other product candidates that we may develop or acquire;

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future clinical trial results of our Neuro-Spinal Scaffold;

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the timing of, and the costs involved in, obtaining regulatory approvals for the Neuro-Spinal Scaffold if our pilot and pivotal studies are successful, and the outcome of regulatory review of the Neuro-Spinal Scaffold;

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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;

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

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

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

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- § 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. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

***Raising additional capital may cause dilution to our 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 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 or any other product candidates that we develop or acquire.

***We license certain technology underlying the development of our Neuro-Spinal Scaffold 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 Massachusetts Institute of Technology, or MIT, that is integrated into our Neuro-Spinal Scaffold under an exclusive license. Under the license agreement, we have agreed to milestone payments and to meet certain reporting obligations. In the event that we were to breach any of the obligations under the agreement and fail to timely cure, BCH and MIT would have the right to terminate the agreement upon notice. In addition, BCH and MIT have the right to terminate our license upon the bankruptcy or receivership of the Company. If we are unable to continue to use or license this technology on reasonable terms, or if this technology fails to operate properly, we may not be able to secure alternatives in a timely manner and our ability to develop our products could be harmed.

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***We depend heavily on the success of one product candidate, Neuro-Spinal Scaffold, which is currently being studied in a pilot study. Even if we obtain favorable clinical results, we may not be able to obtain regulatory approval for, or successfully commercialize, our Neuro-Spinal Scaffold.***

We currently have only one product candidate, Neuro-Spinal Scaffold, 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, which is currently being studied in an ongoing pilot study, will require substantial additional clinical development, testing, manufacturing process development, and regulatory approval before we are permitted to commence its commercialization. Our other product candidate, Bioengineered Neural Tissue, is in preclinical development. The clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidates. 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, at least 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 approval for our product candidates, 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.

***We may experience delays in our ongoing pilot study for our Neuro-Spinal Scaffold, and we do not know whether future clinical trials of our Neuro-Spinal Scaffold, or other future product candidates, will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all.***

Before we can obtain regulatory approval for the sale of our Neuro-Spinal Scaffold, we must complete pilot and pivotal clinical studies. Our Neuro-Spinal Scaffold is currently being studied in an early feasibility, five subject pilot study under our approved IDE application for the treatment of complete traumatic acute spinal cord injury. Our preclinical testing to date has been limited in nature and we cannot predict whether more extensive clinical testing will obtain similar results. Even if the initial results of our clinical studies in humans are promising, our results may subsequently fail to meet the safety and efficacy standards required to obtain regulatory approvals. Our pilot clinical study 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 efficacy of our Neuro-Spinal Scaffold, lack of adequate funding to continue the clinical trial, or unforeseen safety issues.

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

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obtain regulatory approval to commence a clinical trial;

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- § 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 institutional review board, or 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 any 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 IRBs at the sites at which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, 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 side effects, or changes in laws or regulations. Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to 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 recruit 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 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.

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.

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***Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and 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 sufficiently produce results to support regulatory applications. We are currently pursuing marketing approval via HDE which requires us to show the device doesn't 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 trials may fail to show safety and probable benefit sufficient to support intended use claims despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidates may not be sufficient to obtain regulatory approval in the United States or elsewhere. It is also possible that patients enrolled in clinical trials will experience adverse 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 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.

Our Neuro-Spinal Scaffold is expected to be regulated as a Class III medical device by the FDA. The FDA-approval process is expensive and can take many years to complete, and we may not be able to demonstrate the safety and efficacy of the Neuro-Spinal Scaffold to the satisfaction of the FDA or the regulatory authorities of other countries. Regulatory agencies may require us to delay, restrict or discontinue clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk, or may also require additional testing. Delays in regulatory approval can be extremely costly in terms of losing any potential marketing advantage of being early to market. Moreover, 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 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 products are not approved, our ability to generate revenues will be limited and our business 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, as well as limitations on the ability to profit from sales of the product.***

Our Neuro-Spinal Scaffold is expected to be regulated by the FDA as a Class III medical device, requiring either PMA or HDE approval. A HUD designation was granted for the Neuro-Spinal

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Scaffold in 2013, opening the HDE pathway. The FDA's approval of an HDE to treat that qualifying patient population then requires demonstration that the device is safe for its intended application, that it is potentially effective, and that the probable benefits outweigh the associated risks. If a competitor device subsequently becomes available through the PMA process that addresses the same patient population as the HDE device, the HDE device may need to be withdrawn from the U.S. market.

In addition, except in certain circumstances, products approved under an HDE cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (i.e., for profit). Currently, a product is only eligible to be sold for profit after receiving HDE approval if the device (1) is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or (2) is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for 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.

***Our medical device 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 products and operations are subject to extensive regulation by the FDA and various other federal, state and foreign governmental authorities. Government regulation of medical devices 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 result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

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

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In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. Modifications to products that are approved through a PMA application 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 application and, although exempt from the effectiveness requirements of a PMA, an HDE does require sufficient information for 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 FDA can delay, limit or deny clearance or approval of a device 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 pre-clinical 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. For example, in 2011, the FDA announced a Plan of Action to modernize and improve the FDA's premarket review of medical devices, and has implemented, and continues to implement, reforms intended to streamline the premarket review process. In addition, as part of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, Congress enacted several reforms entitled the Medical Device Regulatory Improvements and additional miscellaneous provisions which will further affect medical device regulation both pre- and post-approval. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products.

Even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct postmarketing 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 regulator to grant future clearances or approvals;





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- §                    withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and/or
- §                    in the most serious cases, criminal penalties.

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

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

Any product for which we obtain clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA. In particular, we and our third-party suppliers will be required to comply with the FDA's 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 or results of operations.

In addition, the FDA audits compliance with the QSR 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 510(k) clearance or premarket approval of new products or modified products;
- §                    withdrawing 510(k) clearances or 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. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

***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

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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 our 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.

***We will 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

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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.

***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.

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.

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

To date, we have manufactured our Neuro-Spinal Scaffold 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, 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 of 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.

***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.

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***We rely upon third parties for laboratory testing, animal and human clinical studies, which exposes us to increased risk.***

We have been, and will continue to be, dependent on third-party CROs to conduct certain of our laboratory testing, animal and human clinical studies. These third parties may not complete testing activities on schedule. 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 pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our product candidates.

***We may encounter difficulties in managing our growth and expanding our operations successfully.***

As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Future growth will impose significant added responsibilities on members of our management. Our future financial performance and our ability to commercialize our Neuro-Spinal Scaffold, if approved, and any other product candidates, and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and, if necessary, sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our Company.

***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 products, the commercial success of our products will depend on, among other things, their acceptance by physicians, patients, third-party payors 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, 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. 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 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 payors 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.

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

We may make acquisitions of businesses, technologies or intellectual property rights that we believe would be necessary, useful or complementary to our current business. Any such acquisition may require assimilation of the operations, products or product candidates and personnel of the acquired business and the training and integration of its employees, and could substantially increase our operating costs, without any offsetting increase in revenue. Acquisitions 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, it is likely we would issue equity securities as a 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 operation 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 operation of the acquired business, or due to amortization or impairment costs for acquired goodwill and other intangible assets.

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

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

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

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

***We are subject to a pending securities class action and related shareholder demands, which could divert management's attention and harm our business.***

We are the subject of a securities class action lawsuit. The lawsuit, filed in July 2014, alleges violations of the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements related to the timing and completion of the clinical study of our Neuro-Spinal Scaffold. In January 2015, we received a purported shareholder demand alleging breach of fiduciary duties allegedly related to the claimed false and misleading statements that are the subject of the securities class action. We believe that this action is without merit and intend to defend it vigorously. No assurance can be provided that we will be successful in defending this claim or that insurance proceeds will be sufficient to cover any liability under such claims. Further, the amount of time that will be required to resolve these lawsuits is unpredictable and these actions 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.

***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 items, if at all. Even if a claim is not successful, defending such a claim would be time-consuming and expensive, may damage our reputation in the marketplace, and would likely divert our management's attention.

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

We are subject to various environmental, health and safety laws and regulations, including those relating to safe working conditions, laboratory and manufacturing practices, the experimental use of

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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.

**Risks Related to Investment in Our Securities**

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

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

- § the status, completion and/or results of our clinical trials;
- § actual or anticipated variations in our operating results;
- § announcements of developments by us or our competitors;
- § regulatory actions regarding our products;
- § announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- § adoption of new accounting standards affecting our industry;
- § additions or departures of key personnel;
- § sales of our common stock or other securities in the open market; and
- § other events or factors, many of which are beyond our control.

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

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

As of March 31, 2015, there were outstanding warrants to purchase 2,059,397 shares of our common stock (on a post-split basis), and outstanding options to purchase 2,604,679 shares of our common stock (on a post-split basis). We expect to issue additional equity awards to compensate employees, consultants and directors, and may issue additional shares to raise capital, to acquire other companies or technologies, to pay for services, or for other corporate purposes. Any such issuances will have the effect of diluting the interest of current stockholders. The future issuance of any such additional shares of common stock may create downward pressure on the trading price of the common stock. There can be no assurance that we will not be required to issue additional shares, warrants or other convertible securities in the future in conjunction with any capital raising efforts, including at a price (or exercise prices) below the price at which shares of our common stock are currently quoted on the NASDAQ Capital Market.

*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



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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 corporations and "interested stockholders" for three years after the interested stockholder first becomes an interested stockholder, unless the corporation's board of directors approves the combination in advance. 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.

**Risks Related to the Offering**

*We will have broad discretion over the use of the proceeds to us from this offering and may apply it to uses that do not improve our operating results or the value of our securities.*

We will have broad discretion to use the net proceeds to us from this offering, and investors will be relying solely on the judgment of our board of directors and management regarding the application of these proceeds. Although we expect to use the net proceeds from this offering for general corporate purposes, we have not allocated these net proceeds for specific purposes. Investors will not have the opportunity, as part of their investment decision, to assess whether the proceeds are being used appropriately. Our use of the proceeds may not improve our operating results or increase the value of the securities being offered hereby.

*If you purchase the common stock sold in this offering, you will experience immediate and substantial dilution in your investment. You will experience further dilution if we issue additional equity securities in future fundraising transactions.*

Since the price per share of our common stock being offered is expected to be substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution with respect to the net tangible book value of the common stock you purchase in this offering. If we issue additional common stock, or securities convertible into or exchangeable or exercisable for common stock, our stockholders, including investors who purchase shares of common stock in this offering, could experience additional dilution, and any such issuances may result in downward pressure on the price of our common stock. See the section entitled "Dilution" on page S-23 of this prospectus supplement for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

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**FORWARD-LOOKING STATEMENTS**

This prospectus supplement, the accompanying prospectus and the information incorporated by reference in this prospectus supplement and the accompanying prospectus contain certain statements that constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements, and are identified by words such as "believe," "anticipate," "expect," "intend," "plan," "may," "seek" and other similar expressions. Forward-looking statements may include, but are not limited to, statements about:

- § our limited operating history and history of net losses;
- § our ability to raise substantial additional capital to finance our planned operations;
- § our ability to successfully commercialize our current and future product candidates, including our Neuro-Spinal Scaffold;
- § our ability to successfully complete clinical trials and obtain and maintain regulatory approval of our product candidates;
- § our ability to protect and maintain our intellectual property and licensing arrangements;
- § market acceptance of our technology and products;
- § our ability to promote, manufacture and sell our products, either directly or through collaborative and other arrangements with third parties; and
- § our ability to attract and retain key personnel.

These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. We discuss many of these risks in greater detail under the heading "Risk Factors" on page S-5 of this prospectus supplement and in our SEC filings. Also, these forward-looking statements represent our estimates and assumptions only as of the date of the document containing the applicable statement.

You should read this prospectus supplement, the accompanying prospectus and the documents we have filed with the SEC that are incorporated by reference into this prospectus supplement and the accompanying prospectus completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in the foregoing documents by these cautionary statements.

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#### **USE OF PROCEEDS**

We plan to use the net proceeds of this offering for general corporate purposes and working capital. We cannot specify with certainty all of the particular uses for the net proceeds to be received from this offering. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds from the sale of these securities. Pending their uses, we intend to invest the net proceeds of this offering in short-term, interest-bearing, investment grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

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Purchasers of our common stock offered by this prospectus supplement and the accompanying prospectus will suffer immediate and substantial dilution in the net tangible book value per share of common stock. Our net tangible book value as of March 31, 2015 was approximately \$10.3 million, or \$0.39 per share of common stock. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of March 31, 2015 (on a post-split basis).

Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers in this offering and the net tangible book value per share of our common stock immediately after this offering. After giving effect to the assumed sale of shares of common stock in the aggregate amount of \$50,000,000 at an assumed public offering price of \$16.82 per share, the last reported sale price of our common stock on July 22, 2015, and after deduction of commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of March 31, 2015 would have been approximately \$58,660,000 or \$ 2.02 per share of common stock. This represents an immediate increase in net tangible book value of \$1.63 per share to our existing stockholders and an immediate dilution in net tangible book value of \$14.80 per share to investors participating in this offering. The following table illustrates this dilution on a per share basis:

Assumed public offering price per share	\$ 16.82
Net tangible book value per share as of March 31, 2015	\$ 0.39
Increase in net tangible book value per share attributable to new investors purchasing our common stock in this offering	\$ 1.63
As adjusted net tangible book value per share as of March 31, 2015, after giving effect to this offering	\$ 2.02
Dilution per share to new investors purchasing our common stock in this offering	\$ 14.80

Changes in the assumed public offering price of \$16.82 per share would not affect our as adjusted net tangible book value after this offering because this offering is currently limited to \$50,000,000. However, each \$1.00 increase (decrease) in the assumed public offering price of \$16.82 per share would increase (decrease) our as adjusted per share net tangible book value after this offering by approximately \$0.01 per share, and the dilution per share to new investors by approximately \$0.99 per share, assuming that the aggregate dollar amount of shares offered by us, as set forth above, remains at \$50,000,000 and after deducting the commissions and estimated offering expenses payable by us. We may also increase or decrease the aggregate dollar amount of shares we are offering from the amount set forth above. The information discussed above is illustrative only and will adjust based on the actual public offering price, the actual number of shares that we offer in this offering, and other terms of this offering determined at the time of each offer and sale.

The above discussion and table are based on 26,011,852 shares of our common stock outstanding as of March 31, 2015 (on a post-split basis) and excludes as of that date:

§ 2,059,397 shares of our common stock issuable upon exercise of outstanding warrants (on a post-split basis), having a weighted average exercise price of \$5.31 per share;

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- § 482,249 shares of our common stock reserved for future issuances under our 2010 Equity Incentive Plan and 401(k) plan (on a post-split basis); and
- § 4,187,500 shares of our common stock approved by our stockholders in June 2015 for future issuances under our 2015 Equity Incentive Plan and Employee Stock Purchase Plan.

To the extent that outstanding options or warrants are exercised, new options or other equity grants are issued under our incentive compensation plans, shares of common stock are sold under our employee stock purchase plan or we otherwise issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering.

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**PLAN OF DISTRIBUTION**

We have entered into a sales agreement with Cowen and Company, LLC, or Cowen, under which we may issue and sell from time to time up to \$50,000,000 of our common stock through Cowen as our sales agent. Sales of the common stock, if any, will be made at market prices by any method that is deemed to be an "at the market offering" as defined in Rule 415 under the Securities Act, including sales made directly on The NASDAQ Capital Market and any other trading market for the common stock, and sales to or through a market maker other than on an exchange. In addition, with our prior written consent, Cowen may also sell our common stock in negotiated transactions.

Cowen will offer the common stock subject to the terms and conditions of the sales agreement on a daily basis or as otherwise agreed upon by us and Cowen. We will designate the maximum amount of common stock to be sold through Cowen on a daily basis or otherwise determine such maximum amount together with Cowen. Subject to the terms and conditions of the sales agreement, Cowen will use its commercially reasonable efforts to sell on our behalf all of the shares of common stock requested to be sold by us. We may instruct Cowen not to sell common stock if the sales cannot be effected at or above the price designated by us in any such instruction. We or Cowen may suspend the offering of the common stock being made through Cowen under the sales agreement upon proper notice to the other party. We and Cowen each have the right, by giving written notice as specified in the sales agreement, to terminate the sales agreement in each party's sole discretion at any time.

The aggregate compensation payable to Cowen as sales agent will be 3.0% of the gross sales price of the shares sold through it pursuant to the sales agreement.

The remaining sales proceeds, after deducting any expenses payable by us and any transaction fees imposed by any governmental, regulatory, or self-regulatory organization in connection with the sales, will equal our net proceeds for the sale of such common stock.

Cowen will provide written confirmation to us following the close of trading on The NASDAQ Capital Market each day in which common stock is sold through it as sales agent under the sales agreement. Each confirmation will include the number of shares of common stock sold through it as sales agent on that day, the gross sales price per share, the net proceeds to us and the compensation payable by us to Cowen.

We will report at least quarterly the number of shares of common stock sold through Cowen under the sales agreement, the net proceeds to us and the compensation paid by us to Cowen in connection with the sales of common stock.

Settlement for sales of common stock will occur, unless the parties agree otherwise, on the third business day that is also a trading day following the date on which any sales were made in return for payment of the net proceeds to us. There is no arrangement for funds to be received in an escrow, trust or similar arrangement.

In connection with the sale of the common stock on our behalf, Cowen will be deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of Cowen will be deemed to be underwriting commissions or discounts. We have agreed in the sales agreement to provide indemnification and contribution to Cowen against certain liabilities, including liabilities under the Securities Act. In addition, we have agreed, under certain circumstances, to reimburse a portion of the expenses of Cowen in connection with this offering in an amount not to exceed \$50,000.

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As sales agent, Cowen will not engage in any transactions that stabilize our common stock. To the extent required by Regulation M, Cowen will not engage in any market making activities involving our common stock while the offering is ongoing under this prospectus.

We estimate that the total expenses of the offering payable by us, excluding commissions payable to Cowen under the sales agreement, will be approximately \$100,000.

This summary of the material provisions of the sales agreement does not purport to be a complete statement of its terms and conditions. A copy of the sales agreement is filed with the SEC and is incorporated by reference into the registration statement of which this prospectus is a part. See "Where You Can Find Additional Information" below.

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**LEGAL MATTERS**

The validity of the securities offered hereby will be passed upon for us by Greenberg Traurig, LLP, Boston, Massachusetts. Certain matters will be passed upon for Cowen by LeClairRyan, A Professional Corporation, Newark, New Jersey.

**EXPERTS**

The financial statements incorporated in this prospectus supplement by reference to the Annual Report on Form 10-K for the year ended December 31, 2014 have been so incorporated in reliance on the report of Wolf & Company, P.C., independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

**WHERE YOU CAN FIND ADDITIONAL INFORMATION**

We file annual, quarterly and other reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at <http://www.sec.gov>. You may also read and copy any document we file at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including any amendments to those reports, and other information that we file with or furnish to the SEC pursuant to Section 13(a) or 15(d) of the Exchange Act can also be accessed free of charge from our website at <http://www.invivotherapeutics.com>. These filings will be available as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information contained on our website is not part of this prospectus supplement.

You should rely only on the information provided in, and incorporated by reference in, this prospectus supplement and the accompanying prospectus and the registration statement. We have not authorized anyone else to provide you with different information. Our securities are not being offered in any state where the offer is not permitted. The information contained in documents that are incorporated by reference in this prospectus supplement is accurate only as of the dates of those documents. Our business, financial condition, results of operations and prospects may have changed since those dates.

**INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE**

The SEC allows us to incorporate by reference information we file with it, which means that we can disclose important information to you by referring you to another document that we have filed separately with the SEC. You should read the information incorporated by reference because it is an important part of this prospectus supplement and the accompanying prospectus. We incorporate by reference the following information or documents that we have filed with the SEC (excluding those portions of any Current Report on Form 8-K that are furnished and not "filed" pursuant to the General Instructions of Form 8-K):

- § our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed on March 11, 2015;
- § our Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed on May 7, 2015;



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§ our Current Reports on Form 8-K filed on January 29, March 24, April 8, April 16 and June 16, 2015 and our Current Report on Form 8-K/A filed on January 29, 2015; and

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

We also incorporate by reference into this prospectus supplement additional documents that we may file with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the completion or termination of the offering, including all such documents we may file with the SEC after the date of the initial registration statement and prior to the effectiveness of the registration statement, but excluding any information deemed furnished and not filed with the SEC. Any statements contained in a previously filed document incorporated by reference into this prospectus supplement is deemed to be modified or superseded for purposes of this prospectus supplement to the extent that a statement contained in this prospectus supplement, or in a subsequently filed document also incorporated by reference herein, modifies or supersedes that statement.

This prospectus supplement may contain information that updates, modifies or is contrary to information in one or more of the documents incorporated by reference in this prospectus supplement. You should rely only on the information incorporated by reference or provided in this prospectus supplement. We have not authorized anyone else to provide you with different information. You should not assume that the information in this prospectus supplement is accurate as of any date other than the date of this prospectus supplement or the date of the documents incorporated by reference in this prospectus supplement.

We will provide to each person, including any beneficial owner, to whom this prospectus supplement is delivered, upon written or oral request, at no cost to the requester, a copy of any and all of the information that is incorporated by reference in this prospectus supplement.

Requests for such documents should be directed to:

InVivo Therapeutics Holdings Corp.  
One Kendall Square, Suite B14402  
Cambridge, Massachusetts 02139  
Attn: Investor Relations  
(617) 863-5500

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PROSPECTUS

## **INVIVO THERAPEUTICS HOLDINGS CORP.**

**\$100,000,000**

### **Common Stock Warrants Units**

This prospectus relates to common stock, warrants and units that we may sell from time to time in one or more offerings up to a total dollar amount of \$100,000,000 on terms to be determined at the time of sale. We will provide specific terms of these securities in supplements to this prospectus. You should read this prospectus and any supplement carefully before you invest. This prospectus may not be used to offer and sell securities unless accompanied by a prospectus supplement for those securities.

Our common stock is quoted on the OTC Bulletin Board under the symbol "NVIV." On May 10, 2013, the last sales price of our common stock as reported on the OTC Bulletin Board was \$3.00 per share.

These securities may be sold directly by us, through dealers or agents designated from time to time, to or through underwriters or through a combination of these methods. See "Plan of Distribution" in this prospectus. We may also describe the plan of distribution for any particular offering of these securities in any applicable prospectus supplement. If any agents, underwriters or dealers are involved in the sale of any securities in respect of which this prospectus is being delivered, we will disclose their names and the nature of our arrangements with them in a prospectus supplement. The net proceeds we expect to receive from any such sale will also be included in a prospectus supplement.

**Investing in our securities involves a high degree of risk. Beginning on page 2, we discuss several "Risk Factors " 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.**

**The date of this prospectus is May 22, 2013.**

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**ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, using a "shelf" registration process. Under this shelf registration process, we may sell any combination of the securities described in this prospectus in one or more offerings up to a total dollar amount of \$100,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the securities being offered and the terms of that offering. The prospectus supplement may also add to, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with the additional information described under the heading "Where You Can Find More Information" carefully before making an investment decision.

You should rely only on the information contained or incorporated by reference in this prospectus or any applicable prospectus supplement. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted.

You should not assume that the information appearing in this prospectus or any applicable prospectus supplement is accurate as of any date other than the date on the front cover of this prospectus or the applicable prospectus supplement, or that the information contained in any document incorporated by reference is accurate as of any date other than the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any prospectus supplement or any sale of a security. Our business, financial condition, results of operations and prospects may have changed since such dates.

Unless the context otherwise requires, the terms "InVivo," "the Company," "our company," "we," "us," "our" and similar names refer collectively to InVivo Therapeutics Holdings Corp. and its subsidiaries.

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**ABOUT INVIVO THERAPEUTICS HOLDINGS CORP.**

We develop and commercialize new technologies for the treatment of spinal cord injuries. Our proprietary technology was co-invented by Robert S. Langer, ScD, Professor at Massachusetts Institute of Technology ("MIT") and Joseph P. Vacanti, MD, affiliated with Massachusetts General Hospital. The intellectual property rights that are the basis for our products are licensed under an exclusive, world-wide license from Children's Medical Center Corporation and MIT.

We intend to create new treatments for spinal cord injuries. Current treatments consist of a collection of approaches that only focus on symptoms of spinal cord injury. To date, we are not aware of any product on the market that addresses the underlying pathology of spinal cord injury.

Currently, there are no successful spinal cord injury treatment options for spinal cord injury patients. We take a different approach to spinal cord injury and focus on protection of the spinal cord and prevention of secondary injury rather than regeneration. Our platform technologies focus on minimizing tissue damage sustained following acute injury and promoting neural plasticity of the spared healthy tissue, which may result in full or partial functional recovery. The technologies encompass multiple strategies involving biomaterials, U.S. Food & Drug Administration approved drugs, growth factors, and human neural stem cells. We believe our approach could become a standard treatment for both acute and chronic spinal cord injuries.

We intend to leverage our primary platform technology to develop and commercialize several products as follows:

A biocompatible polymer scaffolding device to treat acute spinal cord injuries.

Biocompatible hydrogels for use as: dural sealants, dural replacements, nerve conduits and for local controlled release of methylprednisolone to treat spinal cord injuries and peripheral nerve injuries.

A biocompatible polymer scaffolding device seeded with autologous human neural stem cells to treat acute and chronic spinal cord injuries.

InVivo Therapeutics Corporation was incorporated on November 28, 2005 under the laws of the State of Delaware and on October 26, 2010 completed a reverse merger transaction with and became a wholly-owned subsidiary of InVivo Therapeutics Holdings Corporation, a company incorporated under the laws of the State of Nevada.

Our principal executive offices are located at One Kendall Square, Suite B14402, Cambridge, Massachusetts 02139, and our telephone number is (617) 863-5500. Our worldwide web address is [www.invivotherapeutics.com](http://www.invivotherapeutics.com). The information on our web site is not incorporated by reference into this prospectus and should not be considered to be part of this prospectus.

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**RISK FACTORS**

Investing in our securities involves significant risks. Please see the risk factors under the heading "Risk Factors" in our most recent Annual Report on Form 10-K, as revised or supplemented by our Quarterly Reports on Form 10-Q filed with the SEC since the filing of our most recent Annual Report on Form 10-K, each of which are on file with the SEC and are incorporated by reference in this prospectus. Before making an investment decision, you should carefully consider these risks as well as other information we include or incorporate by reference in this prospectus and any prospectus supplement. The risks and uncertainties we have described are not the only ones facing our company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business operations.

**WHERE YOU CAN FIND MORE INFORMATION**

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any document we file at the SEC's public reference room at 100 F Street, N.E., Washington, DC 20549. You should call 1-800-SEC-0330 for more information on the operation of the public reference room. Our SEC filings are also available to you on the SEC's Internet site at [www.sec.gov](http://www.sec.gov).

This prospectus is part of a registration statement that we filed with the SEC. This prospectus does not contain all of the information included in the registration statement, including certain exhibits and schedules. You can obtain a copy of the registration statement and exhibits from the SEC at the address listed above or from the SEC's Internet site.

Our Internet address is [www.invivotherapeutics.com](http://www.invivotherapeutics.com). The information on our Internet website is not incorporated by reference in this prospectus or any prospectus supplement.

**SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION**

This prospectus and each prospectus supplement includes and incorporates forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements, other than statements of historical facts, included or incorporated in this prospectus or any prospectus supplement regarding our strategy, future operations, financial position, future revenues and earnings, projected margins and expenses, prospects, potential acquisitions or strategic alliances, plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. There are a number of important factors that could cause our actual results to differ materially from those indicated by these forward-looking statements. These important factors include the factors that we identify in the documents we incorporate by reference in this prospectus, as well as other information we include or incorporate by reference in this prospectus and any prospectus supplement. Please see the factors described under the heading "Risk Factors" of this prospectus. You should read these factors and other cautionary statements made in this prospectus and any accompanying prospectus supplement, and in the documents we incorporate by reference as being applicable to all related forward-looking statements wherever they appear in the prospectus and any accompanying prospectus supplement, and in the documents incorporated by reference. We do not assume any obligation to update any forward-looking statements made by us.

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**INCORPORATION OF CERTAIN INFORMATION BY REFERENCE**

The SEC allows us to "incorporate" into this prospectus information and reports that we file with the SEC. This means that we can disclose important information to you by referring to other documents that contain that information. Any information that we incorporate by reference is considered part of this prospectus. The documents and reports that we list below are incorporated by reference into this prospectus, other than any portion of any such documents that are not deemed "filed" under the Exchange Act in accordance with the Exchange Act and applicable SEC rules.

In addition, all documents and reports which we file pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus and prior to the termination of the offering made hereby are incorporated by reference in this prospectus as of the respective filing dates of these documents and reports.

We have filed the following documents with the SEC. These documents are incorporated herein by reference as of their respective dates of filing:

- (1) Our Annual Report on Form 10-K for the fiscal year ended December 31, 2012, filed on March 12, 2013;
- (2) Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2013, filed on May 9, 2013;
- (3) Our Current Report on Form 8-K filed on April 17, 2013;
- (4) All of our filings pursuant to the Exchange Act after the date of filing the initial registration statement and prior to the effectiveness of the registration statement; and
- (5) The description of our common stock contained in our Registration Statement on Form 8-A filed on June 30, 2006, including any amendments or reports filed for the purpose of updating such description.

You may request a copy of these documents, which will be provided to you at no cost, by writing or telephoning us at:

InVivo Therapeutics Holdings Corp.  
One Kendall Square, Suite B14402  
Cambridge, Massachusetts 02139  
Attn: Investor Relations  
(617) 863-5500

Statements contained in documents that we file with the SEC and that are incorporated by reference in this prospectus will automatically update and supersede information contained in this prospectus, including information in previously filed documents or reports that have been incorporated by reference in this prospectus, to the extent the new information differs from or is inconsistent with the old information. Any statement so modified or superseded will not be deemed to be a part of this prospectus or any prospectus supplement, except as so modified or superseded. Because information that we later file with the SEC will update and supersede previously incorporated information, you should look at all of the SEC filings that we incorporate by reference to determine if any of the statements in this prospectus or any prospectus supplement or in any documents previously incorporated by reference have been modified or superseded.

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**USE OF PROCEEDS**

We currently intend to use the estimated net proceeds from the sale of these securities for general corporate purposes, which may include the following:

the research, development and pre-clinical and clinical trials for our product candidates;

the acquisition of other companies, businesses, products or technologies;

the repayment and refinancing of debt;

capital expenditures;

working capital; and

any other purpose that we may specify in any prospectus supplement.

We have not yet determined the amount of net proceeds to be used specifically for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds from the sale of these securities. Pending any use, as described above, we intend to invest the net proceeds in high-quality, short-term, interest-bearing securities. Our plans to use the estimated net proceeds from the sale of these securities may change, and if they do, we will update this information in a prospectus supplement.

**THE SECURITIES WE MAY OFFER**

The descriptions of the securities contained in this prospectus, together with the applicable prospectus supplements, summarize the material terms and provisions of the various types of securities that we may offer. We will describe in the applicable prospectus supplement relating to any securities the particular terms of the securities offered by that prospectus supplement. If we so indicate in the applicable prospectus supplement, the terms of the securities may differ from the terms we have summarized below. We will also include in the prospectus supplement information, where applicable, about material United States federal income tax considerations relating to the securities, and the securities exchange, if any, on which the securities will be listed.

We may sell from time to time, in one or more offerings:

common stock;

warrants to purchase common stock or units;

units comprised of common stock and warrants; or

any combination of the foregoing securities.

In this prospectus, we refer to the common stock, warrants and units collectively as "securities." The total dollar amount of all securities that we may issue will not exceed \$100,000,000.

This prospectus may not be used to consummate a sale of securities unless it is accompanied by a prospectus supplement.

#### **DESCRIPTION OF COMMON STOCK**

The following is a description of the material terms and provisions of our common stock. It may not contain all the information that is important to you. You can access complete information by referring to our articles of incorporation and bylaws.

Under our articles of incorporation, we have authority to issue 200,000,000 shares of common stock, par value \$0.00001 per share. As of March 31, 2013, there were 66,193,229 shares of common stock issued and outstanding. All shares of common stock will, when issued, be duly authorized, fully



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paid and nonassessable. 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.

In addition, as of March 31, 2013:

there were outstanding warrants to purchase an aggregate of up to 15,400,787 shares of our common stock at a weighted average exercise price of \$1.36 per share;

there were an aggregate of 9,495,626 shares of our common stock subject to outstanding stock options at a weighted average exercise price of \$1.40 per share; and

1,512,042 shares of our common stock were reserved for future issuances under our incentive compensation plans and 401(k) plan.

The holders of common stock are entitled to one vote per share on all matters submitted to a vote of the stockholders, including the election of directors. 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. 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. The holders of common stock will be entitled to such cash dividends as may be declared from time to time by the Board from funds available. The holders of common stock have no preferential or preemptive right and no subscription, redemption or conversion privileges with respect to the issuance of additional shares of our common stock. Upon liquidation, dissolution or winding up of the Company, the holders of common stock will be entitled to receive pro rata all assets available for distribution to such holders after payment of our liabilities.

**Registrar and Transfer Agent**

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

**Trading Market**

Our common stock is quoted on the OTC Bulletin Board under the symbol "NVIV."

**DESCRIPTION OF WARRANTS**

We may issue warrants for the purchase of common stock or units. Warrants may be issued independently or together with common stock or units, and the warrants may be attached to or separate from such securities. We may issue warrants directly or under a warrant agreement to be entered into between us and a warrant agent. We will name any warrant agent in the applicable prospectus supplement. Any warrant agent will act solely as our agent in connection with the warrants of a particular series and will not assume any obligation or relationship of agency or trust for or with any holders or beneficial owners of warrants.

The following is a description of the general terms and provisions of any warrants we may issue and may not contain all the information that is important to you. You can access complete information by referring to the applicable prospectus supplement. In the applicable prospectus supplement, we will describe the terms of the warrants and any applicable warrant agreement, including, where applicable, the following:

the title of the warrants;

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the offering price and aggregate number of warrants offered;

the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security;

the date on and after which the warrants and the related securities will be separately transferable;

any information with respect to book-entry procedures;

in the case of warrants to purchase common stock or units, the number of shares of common stock or units, as the case may be, purchasable upon the exercise of one warrant and the price at which these securities may be purchased upon such exercise;

the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement and the warrants;

the terms of any rights to redeem or call the warrants;

any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;

the dates on which the right to exercise the warrants will commence and expire;

the manner in which the warrant agreement and warrants may be modified;

a discussion of any material U.S. federal income tax considerations of holding or exercising the warrants;

the terms of the securities issuable upon exercise of the warrants; and

any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

#### **DESCRIPTION OF UNITS**

The following description, together with the additional information we include in any applicable prospectus supplement, summarizes the material terms and provisions of the units that we may offer under this prospectus. Units may be offered independently or together with common stock and warrants offered by any prospectus supplement, and may be attached to or separate from those securities.

While the terms we have summarized below will generally apply to any future units that we may offer under this prospectus, we will describe the particular terms of any series of units that we may offer in more detail in the applicable prospectus supplement. The terms of any units offered under a prospectus supplement may differ from the terms described below.

We will incorporate by reference into the registration statement of which this prospectus is a part the form of unit agreement, including a form of unit certificate, if any, that describes the terms of the series of units we are offering before the issuance of the related series of units. The

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following summaries of material provisions of the units and the unit agreements are subject to, and qualified in their entirety by reference to, all the provisions of the unit agreement applicable to a particular series of units. We urge you to read the applicable prospectus supplements related to the units that we sell under this prospectus, as well as the complete unit agreements that contain the terms of the units.

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**General**

We may issue units consisting of common stock and warrants. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time, or at any time before a specified date.

We will describe in the applicable prospectus supplement the terms of the series of units, including the following:

the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;

any provisions of the governing unit agreement that differ from those described below; and

any provisions for the issuance, payment, settlement, transfer, or exchange of the units or of the securities comprising the units.

The provisions described in this section, as well as those described under "Description of Common Stock," and "Description of Warrants," will apply to each unit and to the common stock and warrants included in each unit, respectively.

**Issuance in Series**

We may issue units in such amounts and in such numerous distinct series as we determine.

**Enforceability of Rights by Holders of Units**

Each unit agent will act solely as our agent under the applicable unit agreement and will not assume any obligation or relationship of agency or trust with any holder of any unit. A single bank or trust company may act as unit agent for more than one series of units. A unit agent will have no duty or responsibility in case of any default by us under the applicable unit agreement or unit, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a unit, without the consent of the related unit agent or the holder of any other unit, may enforce by appropriate legal action its rights as holder under any security included in the unit.

**Title**

We, the unit agent, and any of their agents may treat the registered holder of any unit certificate as an absolute owner of the units evidenced by that certificate for any purposes and as the person entitled to exercise the rights attaching to the units so requested, despite any notice to the contrary.

**CERTAIN ANTI-TAKEOVER AND INDEMNIFICATION PROVISIONS OF  
OUR ARTICLES OF INCORPORATION, BY-LAWS AND NEVADA LAW**

**Anti-Takeover Effects of Provisions of Nevada State Law**

We may be or in the future 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. We currently have less than 100 stockholders of record who are residents of Nevada.

The control share law focuses on the acquisition of a "controlling interest," which means the ownership of outstanding voting shares that would be sufficient, but for the operation of the control



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share law, to enable the acquiring person to exercise the following proportions of the voting power of the corporation in the election of directors: (1) one-fifth or more but less than one-third; (2) one-third or more but less than a majority; or (3) a majority or more. The ability to exercise this voting power may be direct or indirect, as well as individual or in association with others.

The effect of the control share law is that an acquiring person, and those acting in association with that person, will obtain only such voting rights in the control shares as are conferred by a resolution of the stockholders of the corporation, approved at a special or annual meeting of stockholders. The control share law contemplates that voting rights will be considered only once by the other stockholders. Thus, there is no authority to take away voting rights from the control shares of an acquiring person once those rights have been approved. If the stockholders do not grant voting rights to the control shares acquired by an acquiring person, those shares do not become permanent non-voting shares. The acquiring person is free to sell the shares to others. If the buyer or buyers of those shares themselves do not acquire a controlling interest, the shares are not governed by the control share law.

If control shares are accorded full voting rights and the acquiring person has acquired control shares with a majority or more of the voting power, a stockholder of record, other than the acquiring person, who did not vote in favor of approval of voting rights, is entitled to demand fair value for such stockholder's shares.

In addition to the control share law, Nevada has a business combination law, which prohibits certain business combinations between Nevada corporations and "interested stockholders" for three years after the interested stockholder first becomes an interested stockholder, unless the corporation's board of directors approves the combination in advance. For purposes of Nevada law, an interested stockholder is any person who is: (a) the beneficial owner, directly or indirectly, of 10% or more of the voting power of the outstanding voting shares of the corporation, or (b) an affiliate or associate of the corporation and at any time within the previous three years was the beneficial owner, directly or indirectly, of 10% or more of the voting power of the then-outstanding shares of the corporation. The definition of "business combination" contained in the statute is sufficiently broad to cover virtually any kind of transaction that would allow a potential acquirer to use the corporation's assets to finance the acquisition or otherwise to benefit its own interests rather than the interests of the corporation and its other stockholders.

The effect of Nevada's business combination law is to potentially discourage parties interested in taking control of the Company from doing so if it cannot obtain the approval of our board of directors.

**Anti-Takeover Effects of Provisions of Our Articles of Incorporation and Bylaws**

Our articles of incorporation provide for a classified board of directors. This provision could prevent a party who acquires control of a majority of our outstanding common stock from obtaining control of the board until our second annual stockholders meeting following the date the acquirer obtains the controlling stock interest. The classified board provision could have the effect of discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us and could increase the likelihood that incumbent directors will retain their positions. In addition, under our amended and restated bylaws, directors may be removed only for cause and only by the affirmative vote of the holders of at least 80% of the voting power of our then outstanding shares of capital stock entitled to vote generally in the election of directors, voting together as a single class.

Our amended and restated bylaws also provide that stockholders may only act at meetings of stockholders and not by written consent in lieu of a stockholders' meeting. Our amended and restated bylaws provide that stockholders may not call a special meeting of stockholders. Rather, only the Chairman of our Board, the President or the Board of Directors pursuant to a resolution approved by a majority of the entire Board of Directors are able to call special meetings of stockholders. Our

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amended and restated bylaws also provide that stockholders may only conduct business at special meetings of stockholders that was specified in the notice of the meeting. These provisions may discourage another person or entity from making a tender offer, even if it acquired a majority of our outstanding voting stock, because the person or entity could only take action at a duly called stockholders' meeting relating to the business specified in the notice of meeting and not by written consent.

**Indemnification of Directors and Officers**

Nevada Revised Statutes ("NRS") Sections 78.7502 and 78.751 provide us with the power to indemnify any of our directors, officers, employees and agents. The person entitled to indemnification must have conducted himself in good faith, and must reasonably believe that his conduct was in, or not opposed to, our best interests. In a criminal action, the director, officer, employee or agent must not have had reasonable cause to believe that his conduct was unlawful.

Under NRS Section 78.751, advances for expenses may be made by agreement if the director or officer affirms in writing to repay the expenses if it is determined that such officer or director is not entitled to be indemnified.

Our bylaws include an indemnification provision under which we have the power to indemnify our directors, officers, former directors and officers, employees and other agents (including heirs and personal representatives) against all costs, charges and expenses actually and reasonably incurred, including an amount paid to settle an action or satisfy a judgment to which a director or officer is made a party by reason of being or having been a director or officer of the Company. Our bylaws further provide for the advancement of all expenses incurred in connection with a proceeding upon receipt of an undertaking by or on behalf of such person to repay such amounts unless it is determined that the party is entitled to be indemnified under our bylaws. No advance will be made by the Company to a party if it is determined that the party acted in bad faith. These indemnification rights are contractual, and as such will continue as to a person who has ceased to be a director, officer, employee or other agent, and will inure to the benefit of the heirs, executors and administrators of such a person. Our bylaws do not eliminate or limit the liability of a director for: (i) an act or omission which involves intentional misconduct, fraud or a knowing violation of law; or (ii) the payment of dividends in violation of NRS 78.300. These provisions may be sufficiently broad to indemnify such persons for liabilities arising under the Securities Act, in which case such provision is against public policy as expressed in the Securities Act and is therefore unenforceable.

We maintain an insurance policy on behalf of our directors and officers, covering certain liabilities which may arise as a result of the actions of the directors and officers.

We have entered into an indemnification agreement with each of our officers and directors pursuant to which they will be indemnified by us, subject to certain limitations, for any liabilities incurred by them in connection with their role as officers and/or directors of the Company.

**PLAN OF DISTRIBUTION**

We may sell the securities being offered hereby in one or more of the following ways from time to time:

directly to investors;

through agents to the public or to investors;

directly to agents;

to one or more underwriters or dealers for resale to the public or to investors;

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in "at the market offerings," within the meaning of Rule 415(a)(4) of the Securities Act, to or through a market maker or into an existing trading market, or an exchange or otherwise; or

through a combination of any of these methods of sale.

The securities that we distribute by any of these methods may be sold, in one or more transactions, at:

a fixed price or prices, which may be changed;

market prices prevailing at the time of sale;

prices related to prevailing market prices; or

negotiated prices.

We will set forth in a prospectus supplement the terms of the offering of our securities, including:

the name or names of any agents or underwriters;

the purchase price of our securities being offered and the proceeds we will receive from the sale;

any over-allotment options under which underwriters may purchase additional securities from us;

any agency fees or underwriting discounts and commissions and other items constituting agents' or underwriters' compensation;

any public offering price;

any discounts or concessions allowed or reallocated or paid to dealers; and

any securities exchanges on which such common stock may be listed.

**Underwriters**

Underwriters, dealers and agents that participate in the distribution of the securities may be underwriters as defined in the Securities Act and any discounts or commissions they receive from us and any profit on their resale of the securities may be treated as underwriting discounts and commissions under the Securities Act. We will identify in the applicable prospectus supplement any underwriters, dealers or agents and will describe their compensation. In no event will the aggregate value of compensation received or to be received by Financial Industry Regulatory Authority members or independent broker-dealers exceed 8% for the sale of the securities registered hereunder. We may have agreements with the underwriters, dealers and agents to indemnify them against specified civil liabilities, including liabilities under the Securities Act. Underwriters, dealers and agents may engage in transactions with or perform services for us or our subsidiaries in the ordinary course of their businesses.



## Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form 424B5

If we use underwriters for a sale of securities, the underwriters will acquire the securities for their own account. The underwriters may resell the securities in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. The obligations of the underwriters to purchase the securities will be subject to the conditions set forth in the applicable underwriting agreement. The underwriters will be obligated to purchase all the securities offered if they purchase any of the securities offered. We may change from time to time any initial public offering price and any discounts or concessions the underwriters allow or reallow or pay to dealers. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement naming the underwriters the nature of any such relationship.

If indicated in the applicable prospectus supplement, we will authorize underwriters or other persons acting as our agents to solicit offers by particular institutions to purchase securities from us at

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the public offering price set forth in such prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on the date or dates stated in such prospectus supplement. Each delayed delivery contract will be for an amount no less than, and the aggregate principal amounts of securities sold under delayed delivery contracts shall be not less nor more than, the respective amounts stated in the applicable prospectus supplement. Institutions with which such contracts, when authorized, may be made include commercial and savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions and others, but will in all cases be subject to our approval. The obligations of any purchaser under any such contract will be subject to the conditions that (a) the purchase of the securities shall not at the time of delivery be prohibited under the laws of any jurisdiction in the United States to which the purchaser is subject, and (b) if the securities are being sold to underwriters, we shall have sold to the underwriters the total principal amount of the securities less the principal amount thereof covered by the contracts. The underwriters and such other agents will not have any responsibility in respect of the validity or performance of such contracts.

**Agents**

We may designate agents who agree to use their reasonable efforts to solicit purchases for the period of their appointment or to sell securities on a continuing basis.

**Direct Sales**

We may also sell securities directly to one or more purchasers without using underwriters or agents. We may also make direct sales through subscription rights distributed to our shareholders on a pro rata basis, which may or may not be transferable. In any distribution of subscription rights to shareholders, if all of the underlying securities are not subscribed for, we may then sell the unsubscribed securities directly to third parties or may engage the services of one or more underwriters, dealers or agents, including standby underwriters, to sell the unsubscribed securities to third parties.

**Trading Markets and Listing of Securities**

Unless otherwise specified in the applicable prospectus supplement, each class or series of securities will be a new issue with no established trading market, other than our common stock, which is quoted on the OTC Bulletin Board. We may elect to list any other class or series of securities on any exchange, but we are not obligated to do so. It is possible that one or more underwriters may make a market in a class or series of securities, but the underwriters will not be obligated to do so and may discontinue any market making at any time without notice. We cannot give any assurance as to the liquidity of the trading market for any of the securities.

**Stabilization Activities**

In connection with an offering, an underwriter may purchase and sell securities in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of securities than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional securities from us, if any, in the offering. If the underwriters have an over-allotment option to purchase additional securities from us, the underwriters may close out any covered short position by either exercising their over-allotment option or purchasing securities in the open market. In determining the source of securities to close out the covered short position, the underwriters may consider, among other things, the price of securities available for purchase in the open market as compared to the price at which they may purchase securities through the over-allotment option. "Naked" short sales are any sales in excess of such option or where the underwriters do not have an over-allotment option. The underwriters must close out any naked short position by purchasing securities in the open market. A naked short position is more likely

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to be created if the underwriters are concerned that there may 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.

Accordingly, to cover these short sales positions or to otherwise stabilize or maintain the price of the securities, the underwriters may bid for or purchase securities in the open market and may impose penalty bids. If penalty bids are imposed, selling concessions allowed to syndicate members or other broker-dealers participating in the offering are reclaimed if securities previously distributed in the offering are repurchased, whether in connection with stabilization transactions or otherwise. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. The impositions of a penalty bid may also effect the price of the securities to the extent that it discourages resale of the securities. The magnitude or effect of any stabilization or other transactions is uncertain. These transactions may be effected on the OTC Bulletin Board or otherwise and, if commenced, may be discontinued at any time.

**EXPERTS**

Our balance sheets as of December 31, 2012 and 2011, and the related statements of operations, changes in stockholders' deficit and cash flows for the years then ended and for the period from November 28, 2005 (inception) to December 31, 2012 have been included herein and in the registration statement in reliance upon the report of Wolf & Company, P.C., independent registered public accountants, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

**LEGAL MATTERS**

Certain legal matters, including the legality of the securities offered, will be passed upon for us by our counsel, Greenberg Traurig, LLP, Boston, Massachusetts. If the securities are distributed in an underwritten offering, certain legal matters will be passed upon for the underwriters by counsel identified in the applicable prospectus supplement.

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**\$50,000,000**

**Common Stock**

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**PROSPECTUS SUPPLEMENT**

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**Cowen and Company**

**July 29, 2015**

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