

INVIVO THERAPEUTICS HOLDINGS CORP.

Form 10-K

March 17, 2014

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2013

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

**FOR THE TRANSITION PERIOD FROM TO
COMMISSION FILE NUMBER 000-52089**

INVIVO THERAPEUTICS HOLDINGS CORP.

(Exact Name of Registrant as specified in its charter)

Nevada
(State or other jurisdiction of
incorporation or organization)

36-4528166
(I.R.S. Employer
Identification No.)

One Kendall Square
Suite B14402 Cambridge, Massachusetts
(Address of principal executive offices)

02139
(Zip Code)

(617) 863-5500

Registrant's telephone number, including area code:

Securities registered pursuant to Section 12(b) of the Act: **None**

Securities registered pursuant to Section 12(g) of the Act:

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Title of each class	
Common Stock, par value \$	0.00001 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer <input type="radio"/>	Accelerated filer <input checked="" type="radio"/>	Non-accelerated filer <input type="radio"/>	Smaller reporting company <input type="radio"/>
(Do not check if a smaller reporting company)			

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates based on the closing price of such stock on the Over-the-Counter Bulletin Board (\$4.13) on June 28, 2013 was \$238,670,234.

As of March 5, 2014, the number of shares outstanding of the registrant's common stock, \$0.00001 par value per share, was 78,994,064.

DOCUMENTS INCORPORATED BY REFERENCE

Designated portions of the Registrant's Proxy Statement for its 2014 Annual Meeting of Stockholders to be filed within 120 days after the Registrant's fiscal year end of December 31, 2013 are incorporated by reference into Part III of this Annual Report.

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**INVIVO THERAPEUTICS HOLDINGS CORP.
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PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains 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"). Statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, regarding future events, our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "might," "will," "should," "intends," "expects," "plans," "goals," "projects," "anticipates," "believes," "estimates," "predicts," "potential," or "continue" or the negative of these terms or other comparable terminology, and include statements about the market potential for treatment of acute spinal cord injury, the sufficiency of our existing capital resources for continuing operations in 2014, the expected effectiveness of our products, and our ability to develop collaborations and partnerships to support our business. These forward-looking statements are only predictions, are uncertain and involve substantial known and unknown risks, uncertainties and other factors which may cause our actual results, levels of activity or performance to be materially different from any future results, levels of activity or performance expressed or implied by these forward-looking statements. Such factors include, among others, the following:

our limited operating history and history of net losses;

our ability to raise substantial additional capital to finance our planned operations;

our ability to successfully commercialize our current and future product candidates, including our bioresorbable polymer scaffold and our bioresorbable hydrogel;

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;

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;

our ability to attract and retain key personnel; and

other factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K and in subsequent filings we make with the Securities and Exchange Commission.

We cannot guarantee future results, levels of activity or performance. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. These cautionary statements should be considered with any written or oral forward-looking statements that we may issue in the future. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to reflect actual results, later events or circumstances or to reflect the occurrence of unanticipated events.

As used herein, "we," "us," "our" or the "Company" means InVivo Therapeutics Holdings Corp., together with its consolidated subsidiaries, unless otherwise noted.

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Item 1. BUSINESS

Overview

We develop novel biomaterial technologies for the treatment of spinal cord injuries and hydrogels for therapeutics delivery. Our proprietary technologies incorporate intellectual property licensed under an exclusive, world-wide license from Children's Medical Center Corporation ("CMCC") and the Massachusetts Institute of Technology ("MIT"), and intellectual property that has been developed internally, including in collaboration with our advisors and partners. At December 31, 2013, we were considered a "development stage enterprise" and will continue to be so until we commence commercial operations. A development stage enterprise is one in which planned principal operations have not commenced or, if its operations have commenced, there has been no significant revenue from operations. Development stage companies report cumulative costs from the date of inception of the enterprise. Our development stage started on November 28, 2005 and continued through December 31, 2013. As of December 31, 2013, we have experienced total net losses since inception of approximately \$81,909,055.

We were incorporated on April 2, 2003, under the name of Design Source, Inc. On October 26, 2010, we acquired the business of InVivo Therapeutics Corporation, which was founded in 2005, and are continuing the existing business operations of InVivo Therapeutics Corporation as our wholly-owned subsidiary.

Our executive offices are located in leased premises at One Kendall Square, Suite B14402 and our phone number is 617-863-5500.

Market Opportunity

Our lead program that we are developing is intended to address the lack of successful treatments for spinal cord injuries. Current treatments for spinal cord injury 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, and we believe that the market opportunity for our technology is significant. Since 1973, the National Spinal Cord Injury Statistical Center ("NSCISC") at the University of Alabama has been commissioned by the US government to maintain a national database of spinal cord injury statistics. In the United States, approximately 273,000 people are currently living with paralysis due to spinal cord injury and an additional 12,000 individuals will become fully or partially paralyzed this year alone. The financial impact of spinal cord injuries, as reported by the NSCISC, is enormous. According to the NSCISC's February 2013 report "Spinal Cord Injury Facts and Figures at a Glance," (i) during the first year, average "cost of care" ranges from \$340,787 to \$1,044,197, depending on the severity of the injury, (ii) the net present value ("NPV") to maintain a quadriplegic injured at age 25 for life is \$4,633,137, and (iii) the NPV to maintain a paraplegic injured at age 25 for life is \$2,265,584. These costs place a tremendous financial burden on families, insurance providers, and government agencies. Moreover, despite all financial investment, the patient remains disabled for life because current medical interventions address only the symptoms of spinal cord injury rather than the underlying neurological cause. We believe our approach could represent an important advance in the treatment for spinal cord injuries.

Product Development

Bioresorbable Polymer Scaffold Device

The first product that we are developing is a poly-L-glutamic acid/poly-L-lysine (PLGA-PLL) scaffold that will be inserted into the spinal cord at the center of the site of injury. The scaffold is

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made of bioresorbable materials that will break down over the course of several months, and incorporates components that promote cell adherence. We believe our scaffold will provide structural support and an environment supportive of cell survival and/or growth.

Because of the complexity of spinal cord injuries, it is likely that multi-modal therapies will be required in order to maximize positive outcomes in spinal cord injury patients. In the future, we may attempt to further enhance the performance of our scaffold by multiple combination strategies involving additional biomaterials, U.S. Food & Drug Administration ("FDA") approved drugs, growth factors, or human neural stem cells.

As noted below, we received a Humanitarian Use Device (HUD) designation for our scaffold and an Investigational Device Exemption (IDE) to begin a pilot clinical trial of our scaffold in 2013.

Pre-clinical Studies

Spinal cord injury (SCI) can result in permanent paralysis, sensory impairment, and autonomic, bowel, bladder, and sexual dysfunction. These functional deficits result from damage to or loss of cells (neurons and glia) in the affected region of the spinal cord, either from the initial mechanical trauma or through secondary mechanisms that persists for several weeks. The ability of potential treatments for SCI to mitigate loss of function or promote recovery can be evaluated in preclinical models using different species and different methods of inducing SCI. In our pre-clinical studies, we utilized both rat and non-human primate models because both exhibit a pattern of neuropathology following SCI that is similar to human SCI. Hemisection injury models, in which sections of spinal cord are surgically removed, are useful in the evaluation of treatment strategies that involve device implantation. Unilateral hemisection models preserve function on one side of the cord, resulting in improved recovery of bladder and bowel function. We therefore evaluated the bioresorbable polymer scaffold device in both rats and non-human primates with unilateral hemisection injury. Because most human SCIs are non-penetrating contusion injuries resulting from rapid compression of spinal tissue by intrusion of bone or disc material following mechanical disruption of the vertebral column, we also evaluated the bioresorbable polymer scaffold device in a rat model of spinal contusion injury.

The first pre-clinical study was conducted by founding scientists of our wholly-owned subsidiary in rats with surgically induced unilateral spinal cord hemisection injury. This study (see Teng, Y. D., Lavik, E. B., Qu, X., Park, K. I., Ourednik, J., Zurakowski, D., Langer, R., and Snyder, E. Y., *Functional recovery following traumatic spinal cord injury mediated by a unique polymer scaffold seeded with neural stem cells*, Proceedings of the National Academy of Sciences 99, pg 3024-3029, 2002) demonstrated the baseline safety and efficacy of porous, biodegradable scaffolds fabricated from PLGA-PLL polymer.

A series of studies in African green monkeys was then performed in order to evaluate the bioresorbable polymer scaffold device in a non-human primate. Our first study in African green monkeys established that unilateral thoracic hemisection SCI (a new model in this species) produced a consistent functional deficit, and we observed a consistently positive response to scaffold implantation (see Pritchard, C. D., Slotkin, J. R., Yu, D., Dai, H., Lawrence, M. S., Bronson, R. T., Reynolds, F. M., Teng, Y. D., Woodard, E. J., and Langer, R. S. *Establishing a model spinal cord injury in the African green monkey for the preclinical evaluation of biodegradable polymer scaffolds seeded with human neural stem cells*, Journal of Neuroscience Methods 188, pg 258-269, 2010). We then conducted two larger studies evaluating the safety and efficacy of the bioresorbable polymer scaffold device in the African green monkey. The extent and time course of functional recovery in biopolymer implant treated primates was assessed with video capture and KinemaTracer evaluation of locomotor behavior with synchronous EMG recording along with locomotor observation rating. When the results of these two studies were combined and analyzed together, we found that implantation of the bioresorbable polymer scaffold device resulted in an increase in remodeled tissue in the region of the hemisection compared

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to non-implant controls, and improved recovery of locomotion in subjects with full unilateral hemisection lesions. A manuscript describing the results from these studies is in preparation.

In parallel with the non-human primate studies, several studies were undertaken to evaluate the safety and efficacy of implantation of the bioresorbable polymer scaffold device following spinal cord contusion injury in rats. Initial studies indicated that 24 hours after contusion injury was an appropriate time for device implantation based on both histological evaluation and ex vivo MRI techniques. Based on these results, a larger rat contusion study was performed at our laboratory. Functional recovery was evaluated with the 21-point Basso, Beattie, and Bresnahan (BBB) locomotor rating scale to assess open field locomotion. In this experiment, the BBB score was not improved by the scaffold device. Taken together, the results from these pre-clinical studies in two injury models in the rat, and in a unilateral hemisection injury in the African green monkey, suggest that implantation of the bioresorbable polymer scaffold device can be tolerated. Further study is ongoing to assess the functional therapeutic potential of the scaffold in animal models of spinal cord contusion injury.

Second-Generation Potential

Because initial pre-clinical studies indicate the potential for use of bioresorbable polymer scaffold devices as part of a strategy to treat SCI, we intend to evaluate second-generation bioresorbable polymer scaffold devices. For example, such second-generation devices might have novel chemistries and geometries that are optimized to support the survival of cell types, like human neural stem cells, that have been shown to promote recovery following implantation in animal models of SCI.

Bioresorbable Hydrogels

We are also developing an injectable, resorbable family of hydrogels for localized, controlled release of small molecules and proteins. Currently as we progress in select pre-clinical activities, we are reaching out to potential biopharmaceutical partners in order to identify collaborations or acquisitions that will maximize the value of our technology in combination with approved and developmental therapeutics. This technology platform encompasses a broad design space with highly tunable chemical and physical properties that allow for precise control of gel formation/degradation and drug release rates. We are exploring the use of this platform in several clinical indications including neurotrauma, postoperative pain, radicular pain, and oncology. Furthermore, there are several opportunities being explored in the neurotrauma space for which the hydrogel technology could be developed as a device only (e.g. dural sealants, dural grafts, adhesion barriers).

A third party holds intellectual property, including patent rights, that may be important or necessary to the development and commercialization of certain of our hydrogel products. Accordingly, it may be necessary for us to use the patented or proprietary technology of third parties to commercialize our hydrogel products, in which case we would be required to obtain a license from such third parties or acquire such intellectual property rights. Alternatively, we can design a work-around solution or challenge the validity of such intellectual property.

Clinical/Regulatory Strategy

Our scaffold is expected to be regulated by the FDA as a Class III medical device. A Class III medical device typically will require FDA approval of a Pre-Market Approval Application (PMA) before we can begin selling the product in the United States. Alternatively, a Class III device may qualify for FDA approval to be distributed under a Humanitarian Device Exemption (HDE) rather than a PMA. In order for a device to be eligible for an HDE, it must be first designated by the FDA as a Humanitarian Use Device (HUD) intended to benefit patients in the treatment or diagnosis of a disease or condition that affects fewer than 4,000 individuals in the United States per year. The HDE also requires there must be no other comparable device available to provide therapy for this condition, and although exempt from the effectiveness requirements of a PMA, does require sufficient

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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.

We are required to conduct human clinical trials before an HDE can be submitted to the FDA to obtain evidence of safety and the probable benefit to health. Before clinical studies can commence, an Investigational Device Exemption application (IDE) must be submitted to and approved by the FDA, and the FDA. The completion of the human clinical studies and obtaining the FDA approval of a PMA could take between three to five years depending on a number of factors including the FDA review and approval process for the IDE and the clinical trial designs, the amount of time it will take to enroll and treat patients in the studies, and the FDA review and approval process for the PMA.

In 2013, the FDA approved our IDE and granted HUD designation for our scaffold. Our scaffold will be studied in an early feasibility, five subject pilot study under our approved IDE. The pilot study will be conducted with staged enrollment requiring a three month wait between consecutive subjects to allow for the monitoring of initial investigational product safety and resorption, because this is a first in human study for this type of device. The pilot study will be conducted in as many as six sites across the United States. As a result of manufacturing issues with respect to the scaffold, the Company expects that its first clinical study site will be ready to enroll subjects in the second quarter of 2014.

Following study design consideration discussions with the FDA, we are also planning a second larger pivotal clinical study in acute spinal cord injury patients.

Even if our pilot and pivotal clinical studies are successful and we are able to obtain FDA approval of a HDE for our scaffold, because the scaffold is a 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. For major markets outside the United States, we would be required to seek regulatory approvals in those markets after the clinical trials are conducted in the United States.

Intellectual Property

We rely on a combination of patents, licenses, trade secrets and non-disclosure agreements to develop, protect and maintain our intellectual property. Our patent portfolio includes patents and patent applications. We seek to develop or obtain intellectual property that we believe might be useful or complementary with our products and technologies, including by way of licenses or acquisitions of other companies or intellectual property from third parties.

As of December 31, 2013, we had filed 12 United States patent applications focused in the areas of our hydrogel technology under development that are at various stages of prosecution. In addition, we hold an exclusive worldwide license to a broad suite of patents co-owned by MIT and CMCC covering the use of a wide range of biopolymers to treat spinal cord injury, and to promote the survival and proliferation of human stem cells in the spinal cord (the "CMCC License"). Pending patent applications licensed under the CMCC License cover the technology underlying our scaffold. Issued patents and pending applications cover the use of a wide range of biomaterial scaffolding as an extracellular matrix substitute for treating spinal cord injury by itself or in combination with drugs, growth factors or human stem cells. The CMCC License covers 7 issued United States patents and 23 issued international patents expiring between 2014 and 2026, and two pending United States patents and 13 pending international patents.

The CMCC License has a 15-year term, or as long as the life of the last expiring patent right, whichever is longer, unless terminated earlier by CMCC. In connection with the CMCC License, we submitted to CMCC and MIT a 5-year plan with certain targets and projections that involve the timing of product development and regulatory approvals. We are required to meet the objectives in the plan, or else we are required to notify CMCC and revise the plan. CMCC has the right to terminate the

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CMCC License for failure by us to either meet the objectives in the plan or submit an acceptable revision to the plan within a 60-day cure period after notification by CMCC that we are not in compliance with the plan. Currently we are in compliance with our plan.

Under the CMCC License, we have the right to sublicense the patents and have full control and authority over the development and commercialization of the licensed products, including clinical trials, manufacturing, marketing, and regulatory filings. We also own the rights to the data generated pursuant to the CMCC License. We have the first right of negotiation for a 30-day period to any improvements to the intellectual property covered by the CMCC License.

We are required to pay certain fees and royalties under the CMCC License. We paid a license issue fee upon execution of the CMCC License and are required to pay a license amendment fee as consideration for the expansion of the field of use. We are also required to make milestone payments upon completing various phases of product development, including upon (i) FDA filing of first investigational new drug application and IDE application; (ii) enrolling first patient in Phase II testing; (iii) enrolling first patient in Phase III testing; (iv) FDA approval of first new drug application or related application, and (v) first market approval in any country outside the United States. Each year prior to the release of a licensed product, we are also required to pay a maintenance fee. Further, we are required to make payments based on sublicenses to manufacturers and distributors. Following commercialization, we are required to make ongoing royalty payments equal to a percentage of net sales of the licensed products.

Competitors

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, designing and implementing clinical trials, regulatory processes and approvals, production and manufacturing, and sales and marketing of approved products. Smaller or early-stage companies and research institutions may also prove to be significant competitors, particularly through collaborative arrangements with large and established biotech or other companies. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and registering subjects for clinical trials.

In order to effectively compete, we will have to make substantial investments in development, 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.

Manufacturing

We have developed a proprietary manufacturing process to build our scaffold. We manufacture our scaffolds following FDA requirements of Design Controls using two fully operational manufacturing cleanrooms located at our Cambridge, Massachusetts facility. These two cleanrooms are validated to ISO 14644-1 Class ISO-7 (Class 10k) and Class ISO-8 (Class 100k) cleanroom standards, respectively. In addition, the manufacturing process contains numerous quality control steps including in-process and final inspection. To date, we have only begun manufacturing our scaffold on a small scale for use in our pilot clinical study. If we are unable to scale up our manufacturing to meet requirements for our pilot or pivotal clinical studies, we may be required to rely on contract manufacturers.

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Sales and Marketing

If we obtain approval to commercialize our products, we plan to sell our products through a to-be-established direct sales force for major markets in the United States and through distributors in foreign markets. The direct sales force would focus its efforts on maximizing revenue through product training, placement and support. We would also seek to establish strong relationships with orthopedic spine surgeons and neurosurgeons and would expect to provide a high level of service for the products including providing on-site assistance and service during procedures. In addition, we expect to establish medical education programs to reach practitioners in physical medicine and rehabilitation centers, and through patient advocacy groups. We may also seek corporate partners with expertise in commercialization.

Compliance with Environmental, Health and Safety Laws

In addition to FDA regulations noted above, we are also subject to evolving federal, state and local environmental, health and safety laws and regulations. In the past, compliance with environmental, health and safety laws and regulations has not had a material effect on our capital expenditures. We believe that we comply in all material respects with existing environmental, health and safety laws and regulations applicable to us.

Employees

We currently have 48 employees, consisting of 45 full-time employees and 3 part-time employees. None of our employees is represented by a labor union, and we consider our employee relations to be good. We also utilize a number of consultants to assist with research and development and regulatory activities. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel.

Availability of Reports

We make available free of charge on or through the Investor Relations link on our website, www.invivotherapeutics.com, all materials that we file electronically with the Securities and Exchange Commission ("SEC"), including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after electronically filing such materials with, or furnishing them to, the SEC. During the period covered by this Form 10-K, we made all such materials available through our website as soon as reasonably practicable after filing such materials with the SEC.

You may also read and copy any materials filed by us with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549, and you may obtain information on the operation of the Public Reference Room by calling the SEC in the United States at 1-800-SEC-0330. In addition, the SEC maintains an Internet website, www.sec.gov, that contains reports, proxy and information statements and other information that we file electronically with the SEC.

Item 1A. RISK FACTORS

Investing in our securities involves significant risks. 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.

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Risks Relating to Our Business

We have a limited operating history and it is difficult to predict our future growth and operating results.

We have a limited operating history and limited operations and assets. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties encountered by companies in the early stage of development, including unforeseen capital requirements and technical problems, delays in obtaining regulatory approvals and failure of market acceptance. As a development stage company, our development timelines have been and may continue to be subject to adjustments that could negatively affect our cash flow and ability to develop or bring products to market, if at all. Predicting our future operating and other results is extremely difficult, if not impossible.

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We have not generated any revenues to date and have a history of losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

We have not generated any revenue to date and, through December 31, 2013, have incurred net losses of \$81,909,055 since inception. It can be expected that we will continue to incur significant operating expenses and continue to experience losses in the foreseeable future. As a result, we cannot predict when, if ever, we might achieve profitability and cannot be certain that we will be able to sustain profitability, if achieved.

There is substantial doubt about our ability to continue as a going concern, which will affect our ability to obtain future financing and may require us to curtail our operations.

Our financial statements as of December 31, 2013 were prepared under the assumption that we will continue as a going concern. The independent registered public accounting firm that audited our 2013 financial statements, in their report, included an explanatory paragraph referring to our recurring losses since inception and expressing substantial doubt in our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. At December 31, 2013, we had cash and cash equivalents of \$13,980,321. Our ability to continue as a going concern depends on our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue.

We will need substantial additional funding to develop our products and for our future operations. If we are unable to obtain the funds necessary to do so, we may be required to delay, scale back or eliminate our product development or may be unable to continue our business.

The development and approval to market and sell our products will require a commitment of substantial funds, in excess of our current capital resources. Before we can market or sell any of our products, we will need to conduct costly and time-consuming research, which includes preclinical and clinical testing and regulatory approvals. We anticipate the amount of operating funds that we use will continue to increase along with our operating expenses over at least the next several years as we plan to bring our products to market. We currently expect that our existing current capital resources will only fund operations through October of 2014. Therefore, we will need to raise substantial capital to develop our products and fund future operations. We cannot be certain that additional financing will be available on acceptable terms, or at all. If we are not successful in raising additional capital, we may not be able to continue as a going concern. To the extent we raise additional capital through the sale of equity securities, the ownership position of our existing stockholders could be substantially diluted. If additional funds are raised through the issuance of preferred stock or debt securities, these securities are likely to have rights, preferences and privileges senior to our common stock. Fluctuating interest rates could also increase the costs of any debt financing we may obtain.

Our products are in an early stage of development and will represent new and rapidly evolving technologies. If we are unable to commercialize our products or experience significant delays in doing so, our business will be materially harmed and we may have to curtail or cease our operations.

Our proprietary spinal cord injury treatment technology depends on new, rapidly evolving technologies and on the marketability and profitability of our products. Approval by applicable regulatory agencies and commercialization of our spinal cord injury treatment technology could fail for a variety of reasons, both within and outside of our control, including the possibility that our products may be ineffective, unsafe or associated with unacceptable side effects, too expensive to develop, manufacture or market, or other parties may hold or acquire proprietary rights that could prevent us or our potential collaborators from developing or marketing our products. Furthermore, because there are no approved treatments for spinal cord injuries, the regulatory requirements governing this type of product may be more rigorous or less clearly established than for other analogous products. If we are

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unable to obtain the required regulatory approvals of our products and subsequently commercialize them, our business will be materially harmed, and we may have to curtail or cease our operations.

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 existing patents and obtain new patents. Some of our proprietary information may not be patentable, and there can be no assurance that others will not utilize similar or superior solutions to compete with us. We cannot guarantee that we will develop proprietary products that are patentable, and that if issued, any patent will give a competitive advantage or that such patent will not be challenged by third parties. The process of obtaining patents can be time consuming with no certainty of success, as a patent may not issue or may not have sufficient scope or strength to protect the intellectual property it was intended to protect. We cannot assure you that our means of protecting our proprietary rights will suffice or that 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 license the technology underlying our scaffold from Children's Medical Center Corporation ("CMCC") and Massachusetts Institute of Technology ("MIT"). If a dispute with CMCC or MIT arises or if we fail to comply with the financial and other terms of the license, we could lose our rights to this license, which would result in a material harm to our business.

We license the technology underlying our scaffold under a patent license from CMCC and MIT. This license agreement imposes certain payment, milestone achievement, reporting, confidentiality and other obligations on us. In the event that we were to breach any of the obligations and fail to cure, CMCC would have the right to terminate this license agreement upon notice. In addition, CMCC has the right to terminate this license upon the bankruptcy or receivership of the Company. The termination of this license would have a material adverse effect on our business, as our current scaffold

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is based on the patents and related intellectual property. If any dispute arises with respect to our arrangement with CMCC or MIT, such dispute may disrupt our operations and would likely have a material and adverse impact on us if resolved in a manner that is unfavorable to us.

We will require 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 biopolymer scaffolding device 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 our products 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. Regulatory authorities may also require additional testing, and we may be required to demonstrate that our proposed products represent an improved form of treatment over existing therapies, which we may be unable to do without conducting further clinical studies. 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 or drugs 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.

If our clinical studies are unsuccessful or significantly delayed, our ability to commercialize our scaffold will be impaired.

Before we can obtain regulatory approval for the sale of our scaffold, we must complete a pilot and pivotal clinical study. Although we have obtained some results from preclinical testing of our intended products in animals, we may not see positive results when any of our scaffold undergoes clinical testing in humans. 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 results of our clinical studies in humans are promising, our scaffold 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 start of the trial, the availability of scaffolds to supply our clinical sites, failure to demonstrate safety and efficacy, unforeseen safety issues, or unforeseen governmental or regulatory delays. Further, regulatory authorities and Institutional Review Boards that must approve and monitor the safety of any clinical study may suspend a clinical study at any time if the patients participating in such study are deemed to be exposed to any unacceptable health risk. Additionally, even if we are able to successfully complete our pilot and pivotal clinical studies, the FDA still may not approve our products.

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Approval to promote, manufacture and sell our products, if granted, is subject to continuing review, which may require the expenditure of substantial resources and subject us to continuing uncertainty.

Even if a product gains regulatory approval, such approval is limited to the patient population studied in our clinical trials, and the product and the manufacture of the product will be subject to continuing regulatory review, including adverse event reporting requirements and the FDA's general prohibition against promoting products for unapproved uses. Failure to comply with any post-approval requirements can, among other things, result in warning letters, product seizures, recalls, substantial fines, injunctions, suspensions or revocations of marketing licenses, operating restrictions and criminal prosecutions. Any of these enforcement actions, any unanticipated changes in existing regulatory requirements or the adoption of new requirements, or any safety issues that arise with any approved products, could adversely affect our ability to market products and generate revenues and thus adversely affect our ability to continue our business.

We also may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or its manufacture are subsequently discovered and we cannot provide assurance that newly discovered or developed safety issues will not arise following any regulatory approval.

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

The biotechnology industry in general 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, designing and implementing clinical trials, regulatory processes and approvals, production and manufacturing, and sales and marketing of approved products.

Large and established companies compete in the biotech 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 through collaborative arrangements with large and established biotech or other companies. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and registering subjects for clinical trials.

In order to effectively compete, we will have to make substantial investments in development, 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

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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 product candidates for several reasons both within and outside of our control.

We have limited experience manufacturing our scaffold for clinical-study scale and no experience for commercial scale.

We have manufactured our scaffold on a small scale, including those that will be needed for our pilot and pivotal clinical studies. We may encounter unanticipated problems in the scale-up process that will result in delays in the manufacturing of the scaffold, and therefore delay our clinical studies. We are subject to IDE FDA regulations requiring manufacturing our scaffolds following 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 may rely on third-party suppliers and vendors for some 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.

We will 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 contract research organizations to conduct some of our laboratory testing, animal and human clinical studies. If we are unable to obtain any necessary testing services on acceptable terms, we may not complete our product development efforts in a timely manner. If we rely on third parties for laboratory testing and animal or human studies, we may lose some control over these activities and become too dependent upon these parties. These third parties may not complete testing activities on schedule or when we request. We may not be able to secure and maintain suitable contract research organizations to conduct our laboratory testing and animal or human studies. We are responsible for confirming that each of our clinical trials is conducted in accordance with our approved plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on 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

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extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our product candidates.

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 these products will depend on, among other things, their acceptance by physicians, patients, third party payers such as health insurance companies and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. If our product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. 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 products do not become widely accepted by physicians, patients, third party payers and other members of the medical community, our business, financial condition and results of operations would be materially and adversely affected.

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.

Physicians and hospitals will require training in order to utilize our products and our success depends upon the acceptance and adoption of our products by physicians and hospitals.

Our products have not been utilized in the past for spinal cord injury treatment. As is typical in the case of a new and rapidly evolving technology or medical treatment, demand and market acceptance for recently introduced products and services are subject to a high level of uncertainty and risk. In addition, physicians and hospitals will need to establish training and procedures to utilize and implement our products. There can be no assurance that these parties will adopt our products or that they develop sufficient training and procedures to properly utilize our products.

If we obtain approval for our products, their commercial success will depend in part upon the level of third party reimbursement 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 the products and related treatments will be available from third-party payers such as

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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.

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 laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and humans, emissions and wastewater discharges, and the use and disposal of hazardous or potentially hazardous substances used in connection with our research. We also cannot accurately predict the extent of regulations that might result from any future legislative or administrative action. 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, development or production efforts.

We face potential product liability, 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 is expensive and sometimes difficult to obtain. We may not be able to obtain or maintain insurance at a reasonable cost. There can be no assurance that existing insurance coverage will extend to other products in the future. Any product liability insurance coverage may not be sufficient to satisfy all liabilities resulting from product liability 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 management's attention.

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 and other 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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Risks Related to Investment in Our Securities

Our securities are "Penny Stock" and subject to specific rules governing their sale to investors.

The SEC has adopted Rule 15c-9 which establishes the definition of a "penny stock," for the purposes relevant to us, as any equity security that has a market price of less than \$5.00 per share or with an exercise price of less than \$5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require that a broker or dealer approve a person's account for transactions in penny stocks; and the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person's account for transactions in penny stocks, the broker or dealer must obtain financial information and investment experience objectives of the person; and make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks. The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form sets forth the basis on which the broker or dealer made the suitability determination; and that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for our shareholders to sell shares of our common stock.

Our common stock is quoted on the OTC Bulletin Board, which may limit the liquidity and price of our common stock more than if our common stock quoted or listed on or a national securities exchange.

Our common stock is currently quoted on the OTC Bulletin Board, an inter-dealer automated quotation system for equity securities not listed on a national securities exchange. Quotation of our common stock on the OTC Bulletin Board may limit the liquidity and price of our common stock more than if our common stock was quoted or listed on a national securities exchange. Some investors may perceive our common stock to be less attractive because they are traded in the over-the-counter market. In addition, as an OTC Bulletin Board company, we do not attract the extensive analyst coverage that accompanies companies listed on a national securities exchange. Further, institutional and other investors may have investment guidelines that restrict or prohibit investing in securities traded in the over-the-counter market. In addition, holders of our common stock may face restrictions on the resale of our common stock due to state "blue sky" laws. These factors may have an adverse impact on the trading and price of our common stock.

Applicable regulatory requirements, including those contained in and issued under the Sarbanes-Oxley Act of 2002, may make it difficult for us to retain or attract qualified officers and directors, which could adversely affect the management of our business and our ability to obtain or retain listing of our common stock.

We may be unable to attract and retain those qualified officers and directors required to provide for effective management because of the rules and regulations that govern publicly held companies. The perceived increased personal risk associated with serving as an officer or director of a publicly held company may deter qualified individuals from accepting roles as directors and executive officers.

In addition, we may have difficulty attracting and retaining directors with the requisite qualifications. If we are unable to attract and retain qualified officers and directors, the management of our business and our ability to obtain or retain listing of our shares of common stock on a national securities exchange (assuming we elect to seek and are successful in obtaining such listing) could be adversely affected.

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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:

actual or anticipated variations in our operating results;

announcements of developments by us or our competitors;

the completion and/or results of our clinical trials;

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;

introduction of new products by us or our competitors;

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 December 31, 2013, there were outstanding warrants to purchase 3,283,134 shares of our common stock, and outstanding options to purchase 8,055,522 shares of our common stock. We expect to issue additional equity awards to compensate employees, consultants and directors, and may issue additional shares to raise capital, to acquire other companies or technologies, to pay for services, or for other corporate purposes. Any such issuances will have the effect of diluting the interest of current stockholders. The future issuance of any such additional shares of common stock may create downward pressure on the trading price of the common stock. There can be no assurance that we will not be required to issue additional shares, warrants or other convertible securities in the future in conjunction with any capital raising efforts, including at a price (or exercise prices) below the price at which shares of our common stock are currently traded on the OTC Bulletin Board.

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 the board of directors into three classes, with three-year staggered terms. The classified board provision could increase the likelihood that, in the event an outside party acquired a controlling block of our stock, incumbent directors nevertheless would retain their positions for a substantial period, which may have the effect of discouraging, delaying or preventing a change in control. In addition, Nevada has a business combination law, which prohibits certain business combinations between Nevada 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

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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 have less than 100 stockholders of record who are residents of Nevada, and are therefore not subject to the control share laws.

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

We have never declared any cash dividends and do not expect to declare any in the near future.

We have never paid cash dividends on our common stock. It is currently anticipated that we will retain earnings, if any, for use in the development of our business and we do not anticipate paying any cash dividends in the foreseeable future.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

On November 30, 2011 and as amended on September 17, 2012, we executed a commercial lease for 26,150 square feet of office, laboratory and manufacturing space in Cambridge, Massachusetts for a period of six years and three months with one five year extension that commenced on June 2012.

Item 3. LEGAL PROCEEDINGS

From time to time we may be named in claims arising in the ordinary course of business. Currently, no legal proceedings, government actions, administrative actions, investigations or claims are pending against us or involve us that, in the opinion of our management, could reasonably be expected to have a material adverse effect on our business and financial condition. We anticipate that we will expend significant financial and managerial resources in the defense of our intellectual property rights in the future if we believe that our rights have been violated. We also anticipate that we will expend significant financial and managerial resources to defend against claims that our products infringe upon the intellectual property rights of third parties.

In November 2013, we filed a lawsuit against Francis Reynolds, the Company's former Chairman, Chief Executive Officer and Chief Financial Officer, in Middlesex Superior Court, Middlesex County, Massachusetts (InVivo Therapeutics Holdings Corp. v. Reynolds, Civil Action No. 13-5004). The complaint alleges breaches of fiduciary duties, breach of contract, conversion, misappropriation of corporate assets, unjust enrichment, corporate waste, and seeks money damages and an accounting. The lawsuit involves approximately \$500,000 worth of personal and/or exorbitant expenses that the Company alleges Mr. Reynolds inappropriately caused the Company to pay while he was serving as the Company's Chief Executive Officer, Chief Financial Officer, President and Chairman of the Board of Directors. On December 6, 2013, Mr. Reynolds answered the complaint, and filed counterclaims against the Company and its Board of Directors. The counterclaims allege two counts of breach of contract, two counts of breach of the covenant of good faith and fair-dealing, and tortious interference with a contract, and seek monetary damages and a declaratory judgment. The counterclaims involve Mr. Reynolds's allegations that the Company and the Board interfered with the performance of his duties under the terms of his employment agreement, and that Mr. Reynolds was entitled to additional shares upon the exercise of certain stock options. On January 9, 2014, the Company and directors named in the counterclaims filed their answer. We expect discovery to begin soon. No judgments or

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rulings are pending at this early stage. We do not believe that the pending actions will materially impact the financial condition of the Company.

On November 8, 2012, we filed a lawsuit (InVivo Therapeutics Corp. v. Beal and Company, Inc., and RB Kendall Fee, LLC, Civil Action No. SUCV2012-04105-A) in Suffolk Superior Court, Suffolk County, Massachusetts. On September 4, 2013, we entered into a settlement agreement and on September 18, 2013, we filed a Stipulation of Dismissal with Suffolk Superior Court which settled this litigation.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Table of Contents**PART II****Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.***Market Information*

Our Common Stock is quoted on the OTC Bulletin Board under the symbol "NVIV." Our shares of Common Stock began being quoted on the OTC Bulletin Board under the symbol "NVIV" effective October 29, 2010.

The following table contains information about the range of high and low bid prices for our Common Stock for each quarter during the last two years based upon quotations on the OTC Bulletin Board.

Fiscal Quarter Ended	High Bid	Low Bid
December 31, 2012	\$ 1.95	\$ 1.28
September 30, 2012	\$ 2.66	\$ 1.36
June 30, 2012	\$ 2.64	\$ 1.96
March 31, 2012	\$ 2.94	\$ 2.00

Fiscal Quarter Ended	High Bid	Low Bid
December 31, 2013	\$ 2.49	\$ 1.08
September 30, 2013	\$ 6.20	\$ 0.94
June 30, 2013	\$ 4.75	\$ 2.20
March 31, 2013	\$ 2.59	\$ 1.61

The source of these high and low prices was the OTC Bulletin Board. These quotations reflect inter-dealer prices, without retail mark-up, markdown or commissions and may not represent actual transactions. The high and low prices listed have been rounded up to the next highest two decimal places.

On March 5, 2014, the closing bid price of our Common Stock as reported by the OTC Bulletin Board was \$2.51 per share.

Trades in the Common Stock may be subject to Rule 15c-9 of the Exchange Act, which imposes requirements on broker/dealers who sell securities subject to the rule to persons other than established customers and accredited investors. For transactions covered by the rule, broker/dealers must make a special suitability determination for purchasers of the securities and receive the purchaser's written agreement to the transaction before the sale.

The SEC also has rules that regulate broker/dealer practices in connection with transactions in "penny stocks." Penny stocks generally are equity securities with a price of less than \$5.00 (other than securities listed on certain national exchanges, provided that the current price and volume information with respect to transactions in that security is provided by the applicable exchange or system). The penny stock rules require a broker/dealer, before effecting a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker/dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker/dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker/dealer and salesperson compensation information, must be given to the customer orally or in writing before effecting the transaction, and must be given to the customer in writing before or with the customer's confirmation. These disclosure requirements may

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have the effect of reducing the level of trading activity in the secondary market for shares of Common Stock. As a result of these rules, investors may find it difficult to sell their shares.

Dividends

We have never declared or paid cash dividends. We do not intend to pay cash dividends on our Common Stock for the foreseeable future, but currently intend to retain any future earnings to fund the development and growth of our business. The payment of cash dividends if any, on the Common Stock will rest solely within the discretion of our board of directors and will depend, among other things, upon our earnings, capital requirements, financial condition, and other relevant factors.

Record Holders

As of March 5, 2014, there are approximately 338 record holders of shares of Common Stock.

Equity Compensation Plans

Information regarding our equity compensation plans and the securities authorized under the plans is included in Item 12 below.

Recent Sales of Unregistered Securities

None

Performance Graph

The graph below compares InVivo Therapeutics Holdings Corp's cumulative 38-Month cumulative total shareholder return on common stock with the cumulative total returns of the NASDAQ Composite index and the NASDAQ Biotechnology index. The graph tracks the performance of a \$100 investment in our common stock and in each index (with the reinvestment of all dividends) from 10/29/2010 to 12/31/2013.

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COMPARISON OF 38 MONTH CUMULATIVE TOTAL RETURN*
Among InVivo Therapeutics Holdings Corp, the NASDAQ Composite Index,
and the NASDAQ Biotechnology Index

*

\$100 invested on 10/29/10 in stock or 10/31/10 in index, including reinvestment of dividends. Fiscal year ending December 31.

	10/29/10	12/10	12/11	12/12	12/13
InVivo Therapeutics Holdings Corp	100.00	83.33	101.85	64.44	85.04
NASDAQ Composite	100.00	105.64	106.11	123.88	175.53
NASDAQ Biotechnology	100.00	101.49	114.21	152.38	259.25

The stock price performance included in this graph is not necessarily indicative of future stock price performance.

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InVivo Therapeutics Holdings Corp.
(A Development Stage Company)
Consolidated Balance Sheets

	December 31,				
	2013	2012	2011	2010	2009
ASSETS :					
Current assets:					
Cash and cash equivalents	\$ 13,980,321	\$ 12,825,090	\$ 4,363,712	\$ 8,964,194	\$ 226,667
Restricted cash	601,471	601,351	547,883		
Prepaid expenses and other current assets	20,087	143,867	104,022	81,166	10,898
 Total current assets	 14,601,879	 13,570,308	 5,015,617	 9,045,360	 237,565
Property and equipment, net	2,337,210	2,311,942	520,482	280,181	173,797
Other assets	157,355	179,415	166,139	53,639	58,639
 Total assets	 \$ 17,096,444	 \$ 16,061,665	 \$ 5,702,238	 \$ 9,379,180	 \$ 470,001
 LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT):					
Current liabilities:					
Accounts payable	\$ 899,260	\$ 1,152,550	\$ 567,195	\$ 336,945	\$ 81,175
Loan payable-current portion	73,987		50,578		
Capital lease payable-current portion	2,799	32,606	30,724		
Derivative warrant liability		14,584,818	35,473,230	10,647,190	
Accrued expenses	1,292,185	1,021,275	618,369	247,547	577,192
 Total current liabilities	 2,268,231	 16,791,249	 36,740,096	 11,231,682	 658,367
Loan payable-less current portion	1,920,000	1,578,000	83,794		590,985
Convertible notes payable					2,840,000
Note payable-less current portion	18,497				
Capital lease payable-less current portion		2,799	38,042		
 Total liabilities	 4,206,728	 18,372,048	 36,861,932	 11,231,682	 4,089,352
 Commitments and contingencies					
Stockholders' equity (deficit):					
Common stock, \$0.00001 par value(1)	788	659	538	516	263
Additional paid-in capital	94,798,231	40,842,339	16,656,830	11,235,829	1,558,283
Deficit accumulated during the development stage	(81,909,303)	(43,153,381)	(47,817,062)	(13,088,847)	(5,177,897)

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Total stockholders' equity (deficit)	12,889,716	(2,310,383)	(31,159,694)	(1,852,502)	(3,619,351)
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Total liabilities and stockholders' equity (deficit)	\$ 17,096,444	\$ 16,061,665	\$ 5,702,238	9,379,180	470,001
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(1)

Authorized 200,000,000 shares; issued and outstanding 78,773,736 & 65,881,122 & 53,760,471 at December 31st, 2013, 2012, and 2011, respectively. Authorized 100,000,000 shares; issued and outstanding 51,647,171 and 26,259,515 shares outstanding at December 31, 2010 and 2009, respectively.

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InVivo Therapeutics Holdings Corp.
(A Development Stage Company)
Consolidated Statement of Operations

	Years Ended December 31,				
	2013	2012	2011	2010	2009
Operating expenses:					
Research and development	\$ 10,533,004	\$ 6,375,795	\$ 4,102,847	\$ 1,673,202	\$ 1,807,908
General and administrative	8,472,197	6,403,656	4,555,872	1,724,102	835,515
Total operating expenses	19,005,201	12,779,451	8,658,719	3,397,304	2,643,423
Operating loss	(19,005,201)	(12,779,451)	(8,658,719)	(3,397,304)	(2,643,423)
Other income (expense):					
Other income					383,000
Interest income	15,279	35,184	8,759	3,379	282
Interest expense	(129,902)	(71,726)	(12,676)	(564,443)	(255,737)
Modification of warrants	(764,769)				
Derivatives gain (loss)	(18,871,329)	17,479,674	(26,065,579)	(3,952,582)	
Other income (expense), net					