INVIVO THERAPEUTICS HOLDINGS CORP.

FORM 10-K
(Annual Report)

Filed 03/12/13 for the Period Ending 12/31/12

Address	ONE KENDALL SQUARE BUILDING 1400 EAST 4TH FLOOR CAMBRIDGE, MA, 02139
Telephone	617-863-5524
CIK	0001292519
Symbol	NVIV
SIC Code	3841 - Surgical and Medical Instruments and Apparatus
Industry	Advanced Medical Equipment & Technology
Sector	Healthcare
Fiscal Year	12/31

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

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2012

☐ **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)**

Registrant's telephone number, including area code: (617) 863-5500

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

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

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 ☐	Accelerated filer ☒
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	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 on June 29, 2012 was $ 92,766,620.

As of March 6, 2013, the number of shares outstanding of the registrant's common stock, $0.00001 par value per share, was 66,146,128.

DOCUMENTS INCORPORATED BY REFERENCE

Designated portions of the Registrant's Proxy Statement for its 2013 Annual Meeting of Stockholders to be filed within 120 days after the Registrant's fiscal year end of December 31, 2012 are incorporated by reference into Part III of this Annual Report.

Explanatory Note: While InVivo Therapeutics Holdings Corp. (the "Company") is no longer a "smaller reporting company" as of the last business day of its most recently completed second fiscal quarter, under the rules and regulations of the Securities and Exchange Commission, the Company may finish reporting using the scaled disclosure afforded to a smaller reporting company for the rest of the fiscal year, including in its Annual Report on Form 10-K. Accordingly, the Company is providing such scaled disclosure in this Annual Report on Form 10-K. As allowed by such rules and regulations, the Company will begin providing the standard non-scaled disclosure in its Quarterly Report on Form 10-Q for the quarter ending March 31, 2013.

Table of Contents

INVIVO THERAPEUTICS HOLDINGS CORP.
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2012
TABLE OF CONTENTS

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, including statements 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, among others, statements about our plan to conduct an initial clinical study to evaluate our product, our estimates regarding the market for treatment of acute spinal cord injury, our expectations regarding the sufficiency of our operating and capital requirements into the first quarter of 2014. These forward-looking statements are only predictions, are uncertain and involve substantial known and unknown risks, uncertainties and other factors which may cause our (or our industry's) 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 ability to raise sufficient capital to finance our planned operations;
- our ability to manage cash expenditures to meet future capital requirements;
- our ability to successfully commercialize our current and future product candidates, including, but not limited to, our biocompatible polymer scaffolding devices and our biocompatible hydrogel;
- our ability to obtain and maintain regulatory approval of our product candidates, including, but not limited to, our biocompatible polymer scaffolding devices and our biocompatible hydrogel, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- market acceptance of our technology and product offerings and the development and commercialization of completing products or therapies;
- our ability to establish and maintain collaborative and other arrangements with third parties to assist in bringing our products to market and the cost of such arrangements;
- our ability to protect our intellectual property;
- our ability to attract and retain key personnel; and
- other factors set forth in the "Risk Factors" section of this Annual Report 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. 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.

Table of Contents

Item 1. BUSINESS

History

We were incorporated on April 2, 2003, under the name of Design Source, Inc. to offer a comprehensive supply of, market and distribute commercial upholstery, drapery, bedspread, panel, and wall covering fabrics to the interior designer industry and individual retail customers on our proprietary Internet website.

We subsequently determined that we could not continue with our intended business operations because of a lack of financial results and resources. We redirected our focus towards identifying and pursuing options regarding the development of a new business plan and direction. On October 26, 2010, we acquired the business of InVivo Therapeutics Corporation, which was co-founded in 2005 by our current Chairman and Chief Executive Officer and are continuing the existing business operations of InVivo as a wholly-owned subsidiary.

Overview

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 ("CMCC") 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 ("FDA") 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.

The Technology

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

1. A biocompatible polymer scaffolding device to treat acute spinal cord injuries.
2. 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.
4. A biocompatible polymer scaffolding device seeded with autologous human neural stem cells to treat acute and chronic spinal cord injuries.

For spinal cord injuries, our biopolymer-based devices are surgically implanted or injected into the lesion created during traumatic injury, or the "primary injury". We expect the biopolymer scaffolding devices will protect the damaged spinal cord by mitigating the progression of "secondary injury" resulting from the body's inflammatory and immune response to injury, and will promote neuroplasticity, a process where functional recovery (the recovery of motor movement or sensation) may occur through the rerouting of signaling pathways to the spared healthy tissue. Achieving these results is essential to the recovery process, as secondary injury can significantly worsen the immediate damage sustained during trauma. The additional damage dramatically reduces patient quality of life post-injury.

Our lead product, the biocompatible polymer scaffolding device to treat acute spinal cord injuries, 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 the Company can start selling the product in the U.S. 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 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. In December 2012, InVivo filed for HUD designation with the FDA for its biopolymer scaffold that, if approved, would permit InVivo to file a subsequent HDE application. The Company received comments from the FDA to the HUD request and responded to the FDA comments in February 2013.

We will be required to demonstrate safety and efficacy in human clinical studies before we can submit a PMA to the FDA. If we obtain the HUD designation from the FDA we will also be 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 the FDA, and the FDA must approve the IDE. We submitted an IDE application for our biopolymer scaffold device to the FDA on July 7, 2011. The FDA has provided comments to our IDE filing and in February 2013, we submitted to the FDA a supplement to the IDE filing. We anticipate that our IDE will be approved by the FDA during 2013, but can give no assurance that the IDE will be approved. We plan to conduct an initial study in five spinal cord patients with acute thoracic injuries followed by a larger study. The FDA must review and approve an HDE or PMA before we can start selling the product in the U.S. 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. The completion of the human clinical studies and FDA approval of a HDE could take potentially less time than as a PMA as we would need to demonstrate only that the probable benefits outweigh the risks for a HDE. The FDA regulatory approval processes can be lengthy and the outcomes are highly uncertain. The risk exists that the first product may never be approved, or that the approval is significantly delayed such that we are unable to raise additional capital to continue to fund the Company. Please see the "Risk Factors" section of this report for a more detailed discussion of these risks.

If the product is approved by the FDA, we will need to expand manufacturing capacity, and establish sales, marketing and distribution channels to sell the product. We intend to retain manufacturing rights and plans to market and sell the product through a direct sales force in the U.S.

We intend to develop a biocompatible hydrogel for the local release of methylprednisolone to treat acute peripheral nerve injuries and spinal cord injuries and a biocompatible polymer scaffolding device seeded with autologous human neural stem cells to treat acute and chronic spinal cord injuries. These two products are likely to be regulated as combination drug/devices and as such will require significantly longer regulatory approval times than the biopolymer scaffolding device. We also intend to develop biocompatible hydrogel devices for use as dural sealants, dural replacements and as nerve conduits.

We are a development stage company, and as such face significant uncertainty regarding our future capital needs and timelines for our intended products.

Market Opportunity-Spinal Cord Injuries

As we are aware of no current products on the market that treat paralysis caused by spinal cord injuries, we believe that our market opportunity for our technology is significant. Based on the Company's estimates, the total addressable market for acute spinal cord injury is approximately $10.4 billion annually. 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 1,275,000 people are currently living with paralysis due to spinal cord injury.
- 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:

- During the first year, average "cost of care" ranges from $334,170 to $1,023,924, depending on the severity.
- The net present value ("NPV") to maintain a quadriplegic injured at age 25 for life is $4,543,182.
- The NPV to maintain a paraplegic injured at age 25 for life is $2,221,596.

Sources: *Christopher & Dana Reeve Foundation, and National Spinal Cord Injury Statistical Center. "One Degree of Separation: Paralysis and Spinal Cord Injury in the United States" 2012.*

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 since current medical interventions address only the symptoms of spinal cord injury rather than the underlying neurological cause.

TABLE 1. COST OF CARE FOR A SPINAL CORD INJURY PATIENT

	AVERAGE YEARLY EXPENSES (in February 2012 dollars)		ESTIMATED LIFETIME COSTS BY AGE AT INJURY (Discounted at 2%)	
SEVERITY OF INJURY	**First Year**	**Each Subsequent Year**	**25 Years Old**	**50 Years Old**
High Tetraplegia (C1-C4) AIS ABC	$1,023,924	$177,808	$4,543,182	$2,496,856
Low Tetraplegia (C5-C8) AIS ABC	$ 739,874	$109,077	$3,319,533	$2,041,809
Paraplegia AIS ABC	$ 499,023	$ 66,106	$2,221,596	$1,457,967
Incomplete Motor Functional at Any Level AIS D	$ 334,170	$ 40,589	$1,517,806	$1,071,309

Source: National Spinal Cord Injury Statistical Center; February 2012 edition of "Spinal Cord Injury Facts and Figures at a Glance." All figures in US Dollars.

Note: tetraplegia is paralysis in the arms, legs and trunk of the body below the level of the spinal cord injury; paraplegia is paralysis of the lower part of the body including the legs.

Creating New Treatments for Spinal Cord Injuries

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

Our goal is to create new options for care by changing the way physicians treat spinal cord injuries. Our technology aims to protect the spinal cord and minimize secondary injury that causes cell death while promoting neural plasticity of the spared healthy tissue, something no other product on the market is designed to do. Our products, if approved for commercialization, will be a new therapeutic class of products and will not compete with current treatment options (i.e. spinal fixation devices). Rather, it is expected that they will be complementary to these products, and the combination may create the best clinical outcome.

Our Lead Product Under Development: A Scaffolding Device to Treat Spinal Cord Injuries

Spinal cord injury involves not only initial cell death at the lesion due to mechanical impact but also a devastating secondary injury pathology that persists for several weeks (Figure 1). We are focused on preventing this secondary cascade of cell death and promoting the subsequent repair and recovery processes.

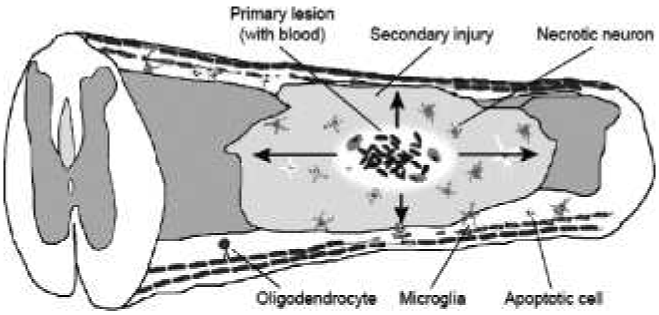

FIGURE 1. PROGRESSION OF SECONDARY INJURY (DAYS 2-30 POST-INJURY) (Fleming *et al.* 2006)

Our lead product is a biopolymer scaffolding device that will be implanted into lesions within the spinal cord to treat acute spinal cord injuries (Figure 2). The porous biopolymer scaffold consists of polylactic-co-glycolic acid (“PLGA”) and-polylysine. PLGA is a biodegradable and biocompatible polymer, which is approved by the FDA for applications such as surgical sutures (Dolphin sutures and Ethicon sutures), drug delivery (Lupron Depot and Sandostatin LAR Depot), and tissue engineering (Dermagraft).

The PLGA-polylysine biopolymer scaffolding device is biocompatible and biodegradable and degrades naturally inside the body without requiring subsequent removal. The device will be customized to fit inside a patient-specific lesion.

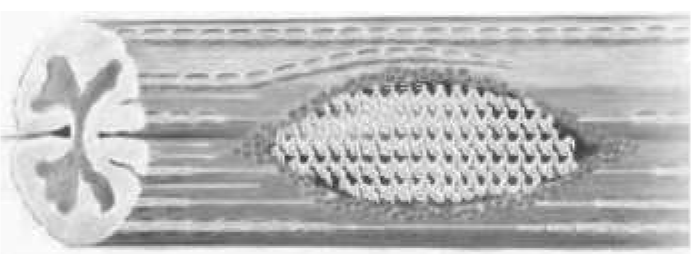

FIGURE 2. SCAFFOLD IMPLANTED INTO SPINAL CORD INJURY LESION

Our biopolymer scaffolding has been designed to prevent and mitigate the cascading inflammatory response or secondary injury and our device is intended to perform four functions:

1. Fill the necrotic lesion to minimize secondary injury, which may occur by inhibiting cell-cell signaling via inflammatory cytokines.

2. Bridge the gap formed by the lesion, providing a matrix designed to promote regrowth and reorganization of neural elements (neurons and neurites).
3. Act as a synthetic extracellular matrix, with the goal of promoting survival of surrounding neurons.
4. Reduce scar formation (astrogliosis).

Our Polymer Technology Differentiator

We intend to introduce the first biodegradable polymer scaffold without any other FDA regulated drugs for spinal cord injury treatment. Since this product does not contain cells or drugs, the implantable device is expected to be regulated as a Class III medical device and as such the FDA approval process should not be as long as a drug or a drug/device combination product.

Local Controlled Release Drug Delivery

We intend to develop is an injectable hydrogel designed to counteract the inflammatory environment that results in peripheral nerve injuries and during a secondary injury from a closed-wound spinal cord injury where further cell death occurs. The hydrogel is designed to release drugs over at least 10 days in order to synchronize the rate of delivery to match the period in which the inflammatory response. While the hydrogel could incorporate other hydrophilic drugs or therapeutic agents that counteract secondary injury, promote neuroplasticity or support endogenous repair mechanisms, our second product is designed to deliver the anti-inflammatory steroid methylprednisolone sodium succinate. Methylprednisolone sodium succinate is FDA-approved, and is currently a treatment option for spinal cord injuries and is used to treat peripheral nerve injuries. However, high-dose intravenous administration of the drug can result in harmful systemic side effects, including increased risks of pneumonia, sepsis and mortality. By precisely controlling the release of methylprednisolone at the site of injury, we hypothesize that therapeutically effective doses can be delivered to the point of inflammation while mitigating the risk of harmful systemic side effects. Although we have conducted initial animal studies for this potential product, we will need to accumulate additional animal data before we can submit for regulatory approval to commence human clinical studies.

Polymer Scaffold Seeded with Autologous Human Neural Stem Cells

We intend to develop an extension of the biopolymer scaffolding platform technology to treat both acute closed-wound and chronic spinal cord injury patients by seeding the patient’s own stem cells onto the scaffold and then inserting the scaffold into the injured spinal cord. The scaffold acts as a synthetic extracellular matrix on which cells can be transplanted.

This product is intended to counteract the pathophysiology of spinal cord injury by:

1. Replacing lost cells of the spinal cord.
2. Activating endogenous regenerative processes such as the formation of new synapses and axonal sprouting based on molecules the stem cells produce.

Although we have conducted initial animal studies for this potential product, we will need to accumulate additional animal data before we can submit for regulatory approval to commence human clinical studies.

[Table of Contents](#)

Rodent Study—2002

The first animal study for our technology was performed by academic researchers at MIT and Harvard Medical School in 2002 and published in the Proceedings of the National Academy of Sciences (PNAS, 2002, vol.99, no.5, 3024-9). The implemented scaffold was designed to mimic the cellular architecture of the inner 'grey' matter and outer 'white' matter of the spinal cord (Figure 3).

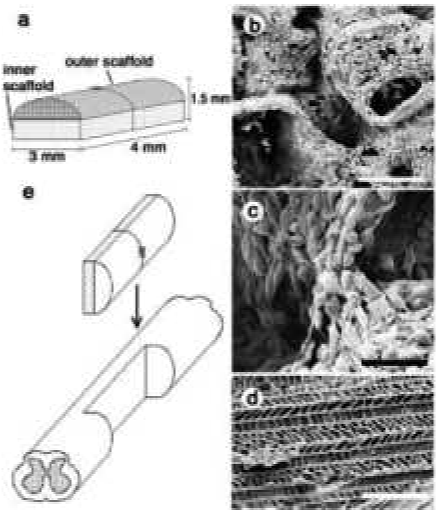

FIGURE 3 (*a*) SCHEMATIC OF THE SCAFFOLD SHOWING INNER AND OUTER ARCHITECTURE. (*b* and *c*) INNER SCAFFOLDS SEEDED WITH HUMAN NEURAL STEM CELL (SCALE: 200 µM AND 50 µM, RESPECTIVELY). THE OUTER SECTION OF THE SCAFFOLD CONTAINS LONG, AXIALLY ORIENTED PORES FOR AXONAL GUIDANCE AS WELL AS RADIAL PORES TO ALLOW FLUID TRANSPORT WHILE INHIBITING THE IN-GROWTH OF SCAR TISSUE (SCALE: 100 µM). (*e*) SCHEMATIC OF SURGICAL INSERTION OF THE IMPLANT INTO THE SPINAL CORD.

The study demonstrated the impact of our polymer-alone device (first product) and our polymer with human neural stem cell device (third product) in treating spinal cord injury (Figure 5). The human neural stem cells augment the polymer scaffolding treatment. The study also demonstrated that stem cells injected into the lesion without our proprietary scaffold do not exert a therapeutic effect. Comparable to the adhesion of cells to the body's extracellular matrix, it is thought that the scaffolding device is necessary for the human neural stem cells to survive and function following transplantation.

The Basso-Beattie-Bresnahan ("BBB") scoring scale was used to evaluate neuromotor (the ability to voluntarily move muscles) improvement at one day post-surgery and weekly time points over the course of six weeks post-injury. The BBB twenty point neuromotor scoring scale evaluates the degree of neuromotor recovery after a spinal cord injury was induced in a spinal cord rodent injury model. For example, a BBB score of zero means the subject has no voluntary motor function after injury, a BBB score of twenty means a complete neuromotor recovery after injury. Results from the PLGA-polylysine scaffold configured to treat spinal cord injury showed neuromotor improvement as early as two weeks post injury. While the study was stopped at the end of either week 8 or week 10, rodents were kept for over one year. The subjects demonstrated neuromotor recovery that was sustained over the year period, and they exhibited no adverse pathological reactions.

Pilot Primate Study—2008

We believe the non-human primate model is the best surrogate for potentially how spinal cord injury products will work in humans. To date, the PLGA-polylysine scaffolding device has been evaluated in two primate studies. The first study involving four primates, was completed in 2008, was published in the Journal of

Neuroscience Methods, and focused mainly on neuromotor assessment criteria following the model spinal cord injury. The second primate study which involved sixteen primates also included collecting quantitative electromyographic and kinematic analyses.

In April 2008, we conducted our first non-human primate study with an induced spinal cord injury model. The experiment was designed as a pilot study to test the model injury in assessing the potential therapeutic efficacy of our technologies. The study was conducted at the St. Kitts Biomedical Research Foundation in St. Kitts and Nevis. The surgeries were performed by Eric Woodard, MD, our Chief Medical Officer, and Jonathan Slotkin, MD. Dr. Woodard served as Chief of Spine Surgery at Harvard's Brigham & Women's Hospital for ten years and is currently Chief of Neurosurgery at Boston's New England Baptist Hospital. Dr. Slotkin has practiced at Harvard's Brigham & Women's Hospital and is currently a spine neurosurgeon at the Washington Brain and Spine Institute and a member of our Scientific Advisory Board.

We utilized a lateral hemisection spinal cord injury model in four African Green monkeys, in which the left-half segment of the spinal cord between T9 and T10 was surgically removed. Immediately following tissue removal, our biopolymer devices were inserted into the resulting lesion by our Chief Medical Officer, Dr. Eric Woodard (Figure 4). The injury model resulted in Brown-Séquard syndrome: paralysis of the animals' left hind limb and loss of sensory function in the animals' right hind limb. The injury model was successful in preserving bowel and bladder function in all animals.

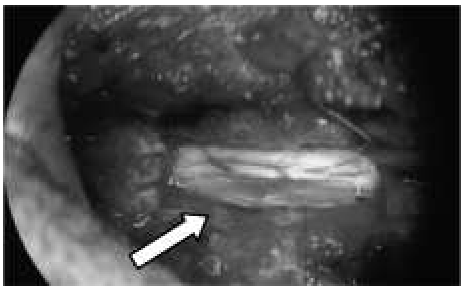

FIGURE 4. DEVICE INSERTED INTO HEMI-SECTION

Animals were monitored for six weeks post-injury, and behavioral scoring was performed to measure functional recovery by a neuroscientist blinded to the injury model or treatments performed on each subject. Preliminary video data of the primates was reviewed and rated by a blinded reviewer not involved in the conduct of the study based on a twenty point neuromotor observational scale developed by InVivo that is analogous to the BBB twenty point neuromotor scale for rodents. InVivo's twenty point scale assesses the degree of neuromotor recovery in the hind-limbs of primates after the lateral hemisection injury model. For example, a score of zero means the primate has no voluntary muscle function after injury, a score of twenty means a completely recovery after injury. Any score greater than eight indicates the subject has regained the ability to bear weight and perform deliberate stepping (Figure 6).

[Table of Contents]

Non-Human Primate Studies: Comparison of Results to Prior Rodent Study

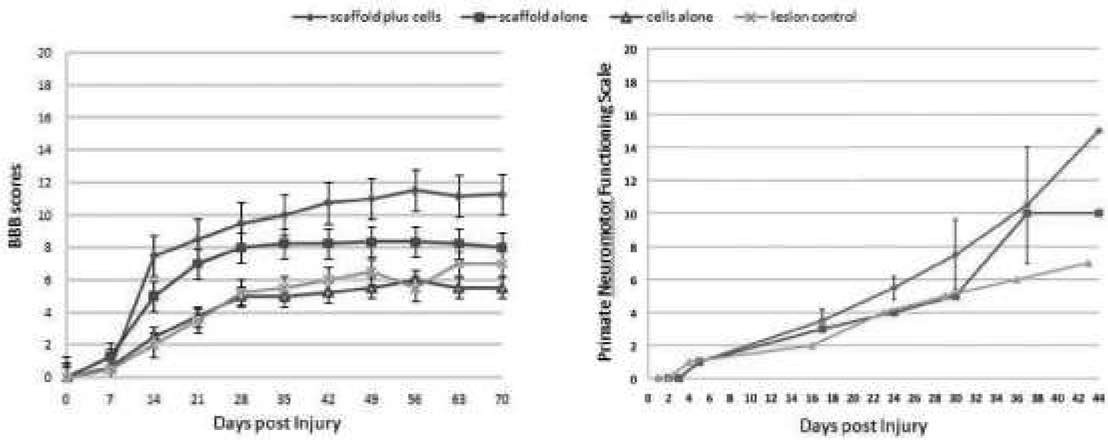

FIGURE 5. IPSILATERAL-LESIONED SIDE BBB OPEN-FIELD WALKING SCORE FROM RODENT STUDY (Teng, Lavik, et al. 2002)

FIGURE 6. LEFT HINDLIMB NEUROMOTOR PERFORMANCE FROM ST. KITTS PRIMATE GREEN PILOT STUDY (2008)
(SCAFFOLD + HNSC: N=2 EXPECT FOR DAY 1 & DAY 44, WHERE N=1; SCAFFOLD-ALONE: N=1, NO TREATMENT: N=1)

The two African Green monkeys that received scaffolds seeded with human neural stem cells (n=2, Figure 6) demonstrated an improved level of functional recovery compared to the control animal (n=1, Figure 6). These results mirrored the behavioral observations obtained in our rodent study (n=12, Figure 5). Furthermore, implantation of the scaffold alone demonstrated improved efficacy in promoting functional recovery compared to the control in both one monkey (n=1, Figure 6) and in prior rodent studies (n=12, Figure 5).

Table of Contents

2 nd Primate Study 2010 – Preclinical evaluation of biomaterial scaffolds and hydrogels in a model spinal cord injury in the African green monkey.

A second primate study involving 16 primates was also conducted at the St. Kitts Biomedical Research Foundation in St. Kitts and Nevis. The surgeries were also performed by Eric Woodard, MD, and Jonathan Slotkin, MD. A segmental thoracic hemisection was used in African green monkeys for the evaluation of biomaterial implants in a pre-clinical model of spinal cord injury in the non-human primate. The model's physiological tolerance permitted behavioral analyses for a 12-week period post-injury, extending to termination points for immunohistochemical analyses.

Implementation of surgically-induced spinal cord injury through T9-T10 thoracic lateral hemisection on 16 African green monkeys with administration of a PLGA-polylysine scaffold (n=4), a PLGA-polylysine scaffold soaked in growth factors (EGF, bFGF, 15 µg each) (n=5), a thiol-acrylate poly (ethylene glycol) based hydrogel containing 150 µg methylprednisolone sodium succinate (n=4), or no treatment for control (n=4). Implants were administered at the time of lesioning. The objective was to determine the feasibility and reliability of this pre-clinical model of spinal cord injury, the safety and efficacy of the implants in a non-human primate model, as well as the establishment of assessment measures. Analysis of functional neuromotor improvements was performed by statistical evaluation of 3D kinematic and electromyographic ("EMG") recordings, InVivo's 0-20 neuromotor scoring system and histological and immunohistochemical stains on post-mortem spinal cord thoracic and lumbar cross-sections.

The neuromotor assessment by a blinded trained neuroscientist for each group over the twelve-week period for the left hind limb was charted (Figure 7). All groups show an initial paralysis 2 days post-injury, confirming successful surgical induction of model Brown-Séquard syndrome. The treatment groups exhibited an improved recovery compared to untreated injured controls on average. Kinematic and EMG analyses exhibited the same trend. While only sixteen primates were evaluated, the initial results are consistent with data from prior monkey and rodent studies.

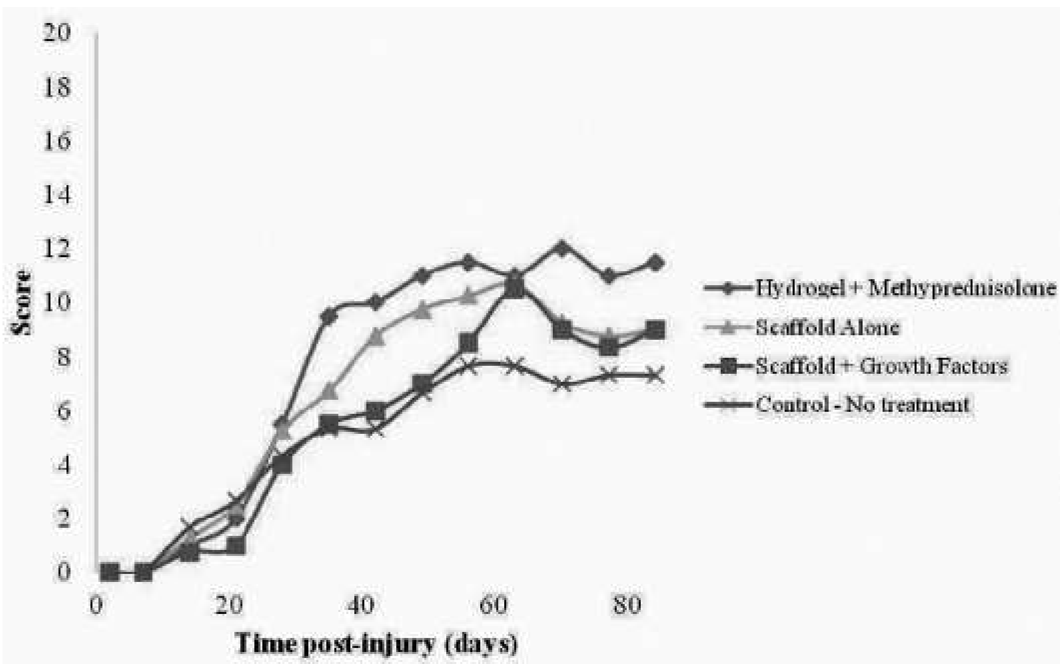

FIGURE 7. IPSILATERAL HINDLIMB TREADMILL HANDCAM NEUROMOTOR SCORE

Table of Contents

3 rd Primate Study 2011: Preclinical evaluation of biomaterial scaffolds and hydrogels in a model spinal cord injury in the African green monkey.

A third primate study was begun in 2011 at the St. Kitts Biomedical Research Foundation in St. Kitts and Nevis. The surgeries were also performed by Eric Woodard, MD, and Jonathan Slotkin, MD. The data collected from this study is intended to support results from previous pre-clinical studies. The study includes 24 additional primates utilizing the same study design as the second African green monkey study. Animals were assigned to one of three groups, including a treatment group (n=8) treated with the PLGA-polylysine scaffold, a treatment group (n=8) treated with the thiol-acrylate poly (ethylene glycol) based hydrogel containing 150 µg methylprednisolone sodium succinate, and a control group (n=8) that received no treatment. Results are consistent with data from prior monkey and rodent studies. The results from the 2011 and 2010 studies are being drafted in a manuscript that will be submitted to a peer-reviewed journal. In both the 2010 and 2011 studies treatment with a PLGA-PLL scaffold resulted in improved functional recovery coupled with the generation of new tissue that was conducive to the growth of axons.

Commercialization Strategy

Clinical Regulatory Plan

Our PLGA biopolymer scaffolding product to treat acute spinal cord injuries is expected to be regulated as a Class III medical device by the FDA. A Class III medical device typically will require FDA approval of a Pre-Market Approval Application (“PMA”) before the Company can start selling the product in the U.S. Alternatively, certain Class III devices can be distributed under a Humanitarian Device Exemption (HDE) rather than a PMA. In order for a device to be eligible for an HDE, a qualifying target patient population of less than 4,000 patients per year for which there is no other available therapy must be approved by the FDA under Humanitarian Use Device (HUD) designation. 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. In December 2012, we filed for HUD designation with the FDA for our biopolymer scaffolding that if approved would permit the Company to file a subsequent HDE application. The Company received comments from the FDA to the HUD request and responded to the FDA comments in February 2013.

We will be required to demonstrate safety and efficacy in human clinical studies before we can submit a PMA, to the FDA. If InVivo obtains the HUD designation from the FDA it will also be required to conduct human clinical trials before an HDE can be submitted to the FDA, but the HDE is exempt from the effectiveness requirements of a PMA. Before human clinical trials can commence , we are required to obtain FDA clearance to conduct the clinical trial under an Investigational Device Exemption application (“IDE”). An IDE application is required by the FDA to include the following information:

- A detailed report of all prior pre-clinical investigations with the device;
- Summary of clinical publications that are relevant to the device;
- An investigational plan for the device that includes the proposed human clinical study protocol; and
- A detailed description of the methods, facilities and controls used for the manufacturing of the device.

Once the IDE has been filed with the FDA, the FDA has a thirty-day period to approve the IDE, or disapprove the IDE, in which case the applicant is provided the opportunity to provide additional information to the FDA to respond to the filing deficiencies. We have conducted a Pre-IDE meeting with the FDA at which we reviewed the pre-clinical data and the clinical trial protocol. At the meeting, the FDA provided the Company observations and guidance concerning the pre-clinical data required for the IDE submission, the description of the manufacturing methods used to make the device and the proposed clinical study protocol. We submitted an IDE to the FDA on July 7, 2011. The FDA has provided us with comments to the IDE filing and in February 2013 we filed a supplement to the IDE. We anticipate that the IDE will be approved by the FDA during 2013, but can give no assurance that the IDE will be approved.

We plan to conduct an initial clinical study to evaluate the device in five spinal cord injury patients with acute thoracic injuries. We are also planning a larger follow-on human study in acute spinal cord injury patients after the initial study is completed. The clinical development timeline is subject to a number of risks that could delay the filing of a HDE or PMA or cause a HDE or PMA never to be filed. The FDA will review the HDE or PMA and there could be significant delays in the review process. There is also a risk that the FDA will never approve the HDE or PMA. These risks are described in the section entitled "Risk Factors" of this Annual Report.

Even if the FDA approves the HDE or PMA for our biopolymer scaffolding product, since this is a new unproven technology, the Company will have significant challenges to demonstrate the clinical utility of the product and gain acceptance from physicians and obtain third party reimbursement for its product. For major markets outside the United States, the Company plans to seek regulatory approvals after the clinical trials are conducted in the United States.

Manufacturing

We have developed a proprietary manufacturing process to create a uniform porous three-dimensional scaffolding structure for each biopolymer scaffolding device. We have established our supply chain and procured the raw material polymers and other components required for manufacturing process. During 2012, we built manufacturing clean room suites in our Cambridge Massachusetts facility and manufactured biopolymer scaffoldings and packaged sterile devices.

Sales and Marketing

We plan to sell our spinal cord injury products through a to-be-established direct sales force for major markets in the U.S and through distributors in foreign markets. Since the product is new, we will seek to gain acceptance with the physicians who are thought leaders in the spinal cord injury field and plan on utilizing a consultative selling approach. The direct sales force will focus its efforts on maximizing revenue through product training, placement and support. We will seek to establish strong relationships with orthopedic spine surgeons and neurosurgeons and expect to provide a high level of service for the products including providing on-site assistance and service during procedures at any time of day. The primary market channel for the product will be to emergency department physicians handling trauma cases. In addition, we will establish medical education programs to reach practitioners in physical medicine and rehabilitation centers, and through patient advocacy groups. We will also utilize Internet and other marketing approaches to reach spinal cord injury patients.

Intellectual Property

In July 2007, InVivo obtained a world-wide exclusive license (the "CMCC 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. In addition, they cover the use of biomaterials in combination with growth factors and drugs. On May 12, 2011, the CMCC License was amended to expand the field of use to include parts of the peripheral nervous system, the cavernous nerve surrounding the prostate, the brain, the retina and cranial nerves. The CMCC License covers 11 issued US patents and 3 pending US patents as well as 34 issued international patents and 23 international patents pending.

The CMCC License provides us intellectual property protection for the use of any biomaterial scaffolding used as an extracellular matrix substitute for treating spinal cord injury by itself or in combination with drugs, growth factors and human stem cells. Our rodent studies have shown that human stem cells cannot proliferate and survive without the addition of the biopolymer scaffolding which serves as an extracellular matrix replacement and mimics the natural cellular architecture of the inner 'grey' and outer 'white' matter of the spinal cord. We believe that any extracellular matrix developed to treat spinal cord injuries will infringe on the patents licensed to us. We intend to defend all patents very aggressively.

The patents are the results of over a decade of research by Dr. Robert S. Langer, Professor of Chemical and Biomedical Engineering at MIT and his research teams at MIT's Langer Lab. Dr. Langer is an inventor who is generally regarded to be the cofounder of the field of tissue engineering.

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

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 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.

We are required to pay certain fees and royalties under the CMCC License. Specifically, we are required to pay a license issue fee, which was paid at the execution of the CMCC License. We are also required to pay a license amendment fee as consideration for the expansion of the field of use and to make milestone payments upon completing various phases of product development, including (i) upon FDA filing of first Investigational New Drug application and Investigational Device Exemption application; (ii) upon enrolling first patient in Phase II testing; (iii) upon enrolling first patient in Phase III testing; (iv) upon filing with the FDA of first New Drug Application or related applications; (v) upon FDA approval of first New Drug Application or related application, and; (vi) upon first market approval in any country outside the US. 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. In addition, following commercialization, we are required to make ongoing royalty payments equal to a percentage of net sales of the licensed products.

Compliance with Environmental, Health and Safety Laws

In addition to FDA regulations, 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. Compliance with environmental, health and safety laws and regulations in the future may require additional capital expenditures.

Employees

We currently have 39 employees, consisting of 36 full-time employees and 3 part-time employees. None of our employees are 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.

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.

Risks Relating to Our Business and Our Industry

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. 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.

Our prospects must be considered in light of inherent risks, expenses and difficulties encountered by all early stage companies, particularly companies in new and evolving markets. These risks include, by way of example and not limitation, unforeseen capital requirements, unforeseen technical problems, delays in obtaining regulatory approvals, failure of market acceptance and competition from foreseen and unforeseen sources.

We have not generated any revenues to date and have a history of losses since inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability.

We have not generated any revenue to date and, through December 31, 2012, have incurred net losses of approximately $43,153,000 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.

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 product candidates 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 will include 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. Our existing current capital resources will fund operations into the first quarter of 2014 and we will need to raise substantial capital to develop our products and fund future operations. Our future capital requirements will depend on many factors, including:

- the progress and costs of our research and development programs, including our ability to develop our current portfolio of therapeutic products, or discover and develop new ones;
- our ability, or our partners ability and willingness, to advance partnered products or programs;
- the cost of prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the progress, scope, costs, and results of our preclinical and clinical testing of any current or future products;
- the time and cost involved in obtaining regulatory approvals;
- the cost of manufacturing our product candidates;
- expenses related to complying with good manufacturing practices and manufacturing of product candidates;
- costs of financing the purchases of additional capital equipment and development technologies;
- competing technological and market developments;

- our ability to establish and maintain collaborative and other arrangements with third parties to assist in bringing our products to market and the cost of such arrangements;
- the amount and timing of payments or equity investments that we receive from collaborators and the timing and amount of expenses we incur;
- costs associated with the integration of any new operation, including costs relating to future mergers and acquisitions with companies that have complementary capabilities;
- expenses related to the establishment of sales and marketing capabilities for products awaiting approval or products that have been approved;
- the level of our sales and marketing expenses; and
- our ability to introduce and sell new products.

We cannot assure you that we will not need additional capital sooner than currently anticipated. We will need to raise substantial additional capital to fund our future operations. We cannot be certain that additional financing will be available on acceptable terms, or at all. In recent years, it has been difficult for companies to raise capital due to a variety of factors, which may or may not continue. 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 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.

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. 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 unable to obtain the required regulatory approvals of our products and subsequently commercialize them, our business will be materially harmed.

We license our core technology 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 patents and core intellectual property from CMCC and MIT under the CMCC license. The CMCC 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 the CMCC license agreement upon notice. In addition, CMCC has the right to terminate the CMCC license agreement upon the bankruptcy or receivership of the Company. The termination of the CMCC license would have a material adverse effect on our business, as all of our current product candidates are based on the patents and licensed 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 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.

Principal competitive factors in our industry include the quality and breadth of an organization's technology; management of the organization and the execution of the organization's strategy; the skill and experience of an organization's employees and its ability to recruit and retain skilled and experienced employees; an organization's intellectual property portfolio; the range of capabilities, from target identification and validation to drug and device discovery and development to manufacturing and marketing; and the availability of substantial capital resources to fund discovery, development and commercialization activities.

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 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 steps required by the FDA before our proposed medical device products may be marketed in the United States include performance of preclinical (animal and laboratory) tests; submissions to the FDA of an Investigational Device Exemption ("IDE") which must become effective before human clinical trials may commence; performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product in the intended target population; performance of a consistent and reproducible manufacturing process intended for commercial use; Human Device Exemption (HDE) or Pre-Market Approval Application ("PMA"); and FDA approval of the HDE or PMA before any commercial sale or shipment of the product.

The processes are 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 such regulatory authorities. The start of clinical trials can be delayed or take longer than anticipated for many and varied reasons, many of which would be outside of our control. All statutes and regulations governing the conduct of clinical trials are subject to change in the future, which could affect the cost of such clinical trials. Safety concerns may emerge that could lengthen the ongoing trials or require additional trials to be conducted. Regulatory agencies may require us or our collaborators 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 lost sales opportunities, losing any potential marketing advantage of being early to market and increased trial costs. 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 product candidates, 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.

The results seen in animal testing of our product candidates may not be replicated in humans, which may significantly delay the commercialization of, or cause us to abandon, our products.

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 product candidates undergo clinical testing in humans in the future. Our preclinical testing to date has been limited in nature and we cannot predict whether more extensive clinical testing will obtain similar results. Success in preclinical studies or completed clinical trials does not ensure that later studies or trials, including continuing preclinical studies and large-scale clinical trials, will be successful nor does it necessarily predict future results. The rate of failure is quite high, and many companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Product candidates may fail to show desired safety and efficacy in larger and more diverse patient populations in later stage clinical trials, despite having progressed through early stage trials. Negative or inconclusive results from any of our ongoing preclinical studies or clinical trials could result in delays, modifications, or abandonment of ongoing or future clinical trials and the termination of our development of a product candidate. Additionally, even if we are able to successfully complete clinical trials, the FDA still may not approve our product candidates.

Our products are in an early stage of development and we currently have no therapeutic products approved for sale. We may be unable to develop or market any of our product candidates. If our product candidates are delayed or fail, our financial condition will be negatively affected, and we may have to curtail or cease our operations.

We currently do not sell any approved therapeutic products and do not expect to have any products commercially available for at least two years, if at all. We are subject to all of the uncertainties and complexities affecting an early stage biotechnology company. Our product candidates require additional research and development. Our strategy of using our technologies for the development of therapeutic products involves new approaches, some of which are unproven. To date, no one to our knowledge has developed or commercialized any therapeutic products using our technologies and we might never commercialize any product using our technologies and strategy. There are many reasons that our product candidates may fail or not advance to commercialization, including the possibility that our product candidates may be ineffective, unsafe or associated with unacceptable side effects; our product candidates may be too expensive to develop, manufacture or market; other parties may hold or acquire proprietary rights that could prevent us or our potential collaborators from developing or marketing our product candidates; physicians, patients, third-party payers or the medical community in general may not accept or use our contemplated products; our potential collaborators may withdraw support for or otherwise impair the development and commercialization of our product candidates; or others may develop equivalent or superior products.

If our current product candidates are delayed or fail, or we fail to successfully develop and commercialize new product candidates, our financial condition will be negatively affected, and we may have to curtail or cease our operations.

Approval to promote, manufacture and/or sell our products, if granted, will be limited and 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 likely to limit the indicated uses for which it may be marketed, and the product and the manufacturer 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. With the use of any treatment by a wide patient population, serious adverse events may occur from time to time that initially do not appear to relate to the treatment itself, and only if the specific event occurs with some regularity over a period of time does the treatment become suspect as having a causal relationship to the adverse event. Any safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenues.

We will be required to obtain international regulatory approval to market and sell our products outside of the United States. The failure to obtain regulatory approval in foreign jurisdictions could harm our business.

We intend to also have our product candidates marketed outside the United States. In order to market products in the European Union and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory agencies in other foreign countries. A failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions, including approval by the FDA. The failure to obtain regulatory approval in foreign jurisdictions could harm our business.

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

We will require quantities of manufactured product and may require third party manufacturers to fulfill some of our inventory requirements. Failure of such third party manufacturers to fulfill their obligations will impair our ability to manufacture our products.

Completion of our clinical trials and commercialization of our products will require access to, or development of, facilities to manufacture a sufficient supply of our product or other product candidates. If we are unable to manufacture our products in commercial quantities, then we will need to rely on third parties. These third-party manufacturers must also receive FDA approval before they can produce clinical material or commercial products. Our products may be in competition with other products for access to these facilities and may be subject to delays in manufacture if third parties give other products greater priority. In addition, we may not be able to enter into any necessary third-party manufacturing arrangements on acceptable terms, or on a timely basis. Failure by us to manufacture products on a timely basis for clinical trials or for commercial needs will have a material adverse effect on us.

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 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 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/or animal and 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/or animal and human studies. We are responsible for confirming that each of our clinical trials is conducted in accordance with our general 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 extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our product candidates.

To date we have performed limited preclinical safety testing of our hydrogel containing methylprednisolone sodium succinate delivered locally to treat spinal cord injuries. The intended product might not be safe for human use. If we cannot demonstrate the product is safe for human use, future development will be halted and the product will never be evaluated in human clinical studies.

Methylprednisolone sodium succinate is a powerful anti-inflammatory drug that is delivered systemically to treat spinal cord injuries. The drug is a corticosteroid administered in high dosage and its use increases the risk of serious adverse effects including pneumonia, sepsis and mortality. Even though we believe that our hydrogel, designed to locally deliver the drug over a period of days will be safer than systemic delivery, to date the combination product has only been evaluated in animal testing on a limited basis. The risk exists that the intended product will have the same serious adverse effects as with systemic delivery and the introduction of the polymer could potentially introduce new side effects.

We will have to demonstrate that this intended product is safe before we can commence human clinical testing. The risk exists that the product will not be safe for human use in which case development would be halted and the product would never be evaluated in human clinical studies.

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 products are new and will require market acceptance. Failure to gain market acceptance would impact our revenues and may materially impair our ability to continue our business.

Even if we receive regulatory approvals for the commercial sale of our product candidates, the commercial success of these product candidates 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 product candidates 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.

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.

Our success will depend upon the level of third party reimbursement for the cost of our products to users.

Our successes may depend, in part, on the extent to which reimbursement for the costs of therapeutic products and related treatments will be available from third-party payers such as government health administration authorities, private health insurers, managed care programs, and other organizations. Over the past decade, the cost of health care has risen significantly, and there have been numerous proposals by legislators, regulators, and third-party health care payers to curb these costs. Some of these proposals have involved limitations on the amount of reimbursement for certain products. Similar federal or state health care legislation may be adopted in the future and any products that we or our collaborators seek to commercialize may not be considered cost-effective. 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 will be 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, including infectious disease agents. 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 must maintain the proprietary nature of our products and must operate without infringing on the proprietary rights of others. We may not be successful in obtaining or maintaining necessary rights for the development and sales of our products.

Our success in large part depends on our ability to maintain the proprietary nature of our licensed technology. We will rely on a combination of patent, trademark, copyright and trade secret laws, as well as confidentiality agreements, license agreements and technical measures to protect our proprietary rights. 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 and services or processes 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, or that the patents of others will not have a material adverse effect on our ability to do business. We intend to register certain trademarks in, or claim certain trademark rights in, the United States and/or foreign jurisdictions. We cannot assure you that our means of protecting our proprietary rights will suffice or that our competitors will not independently develop competitive technology or duplicate processes or design around patents or other intellectual property rights issued to us.

We also must operate without infringing the proprietary rights of third parties or allowing third parties to infringe our rights. Our research, development and commercialization activities, including any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents owned by third parties and to which we do not hold licenses or other rights. 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, development, manufacturing or sales of the product or biologic treatment candidate that is the subject of the suit.

In addition, competitors may infringe our patents or the patents of our collaborators or licensors. As a result, we may be required to file infringement claims to counter infringement for unauthorized use. This can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent licensed or owned by us is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our licensed or owned patents do not cover its technology. An adverse determination of any litigation or defense proceedings could put one or more of our licensed or owned patents at risk of being invalidated or interpreted narrowly and could put our licensed or owned patent applications at the risk of not issuing.

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 be required to raise additional capital to continue in the future to complete clinical trials, obtain marketing approvals and commercialize our products. Our inability to raise capital when needed may cause us to delay, scale back or eliminate our product development or to discontinue our business.

We will be required in the future to raise additional capital to fund our operations. Traditionally, biotech companies have funded their research and development expenditures through raising capital in the equity markets. We will require significant capital beyond our current resources for research and development for our product candidates and clinical trials. The general economic and capital market conditions in the United States and worldwide at the time we seek to raise capital will have an impact on our ability to access capital, and may increase the cost of capital. If economic conditions worsen or the equity markets decline, our future cost of equity or debt capital and access to the capital markets could be adversely affected.

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

We depend on our senior executive officers 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 the principal members of our 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.

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 15g-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.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

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.

Because we became public by means of a reverse merger, we may not be able to attract the attention of major brokerage firms.

Additional risks may exist since we became public through a “reverse merger.” Securities analysts of major brokerage firms may not provide coverage of us since there is little incentive to brokerage firms to recommend the purchase of our common stock. No assurance can be given that brokerage firms will want to conduct any secondary offerings on our behalf in the future.

We face costs and risks associated with maintaining effective internal controls over financial reporting, and if we fail to achieve and maintain adequate internal controls over financial reporting, our business, results of operations and financial condition, and investors’ confidence in us could be materially affected.

Under Sections 302 and 404 of the Sarbanes-Oxley Act of 2002, our management is required to make certain assessments and certifications regarding our disclosure controls and internal controls over financial reporting. We have dedicated, and expect to continue to dedicate, significant management, financial and other resources in connection with our compliance with Section 404 of the Sarbanes-Oxley Act. The process of maintaining and evaluating the effectiveness of these controls is expensive, time-consuming and requires significant attention from our management and staff. During the course of our evaluation, we may identify areas requiring improvement and may be required to design enhanced processes and controls to address issues identified through this review. This could result in significant delays and costs to us and require us to divert substantial resources, including management time from other activities.

If we fail to maintain an effective system of disclosure controls or internal control over financial reporting, we may not be able to rely on the integrity of our financial results, which could result in inaccurate or late reporting of our financial results and investigation by regulatory authorities. If we fail to achieve and maintain adequate internal controls the financial position of our business could be harmed; current and potential future shareholders could lose confidence in us and/or our reported financial results, which may cause a negative effect on the trading price of our common stock; and we could be exposed to litigation or regulatory proceedings, which may be costly or divert management attention.

In addition, all internal control systems, no matter how well designed and operated, can only provide reasonable assurance that the objectives of the control system are met. Because there are inherent limitations in all control systems, no evaluation of control can provide absolute assurance, that all control issues and instances of fraud, if any, within the Company have been or will be detected. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Any failure of our internal control systems to be effective could adversely affect our business.

We do not currently have a separate Chief Financial Officer.

We do not currently have a separate Chief Financial Officer. Our Chief Executive Officer is also functioning as our Chief Financial Officer. Although we are currently seeking to retain a Chief Financial Officer, there can be no assurance we will be able to retain a suitable candidate on acceptable terms.

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, directors and members of board committees required to provide for effective management because of the rules and regulations that govern publicly held companies, including, but not limited to, certifications by principal executive officers. The enactment of the Sarbanes-Oxley Act has resulted in the issuance of a series of related rules and regulations and the strengthening of existing rules and regulations by the SEC, as well as the adoption of new and more stringent rules by the stock exchanges. The perceived increased personal risk associated with these changes may deter qualified individuals from accepting roles as directors and executive officers.

Further, some of these changes heighten the requirements for board or committee membership, particularly with respect to an individual's independence from the corporation and level of experience in finance and accounting matters. 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 any stock exchange (assuming we elect to seek and are successful in obtaining such listing) could be adversely affected.

We may have undisclosed liabilities and any such liabilities could harm our revenues, business, prospects, financial condition and results of operations.

Even though the assets and liabilities of our predecessor company, Design Source, Inc. were transferred to the Split-Off Shareholders in the Split-Off and were not assumed by us, there can be no assurance that we will not be liable for any or all of such liabilities. Any such liabilities that survive the Split-Off could harm our revenues, business, prospects, financial condition and results of operations upon our acceptance of responsibility for such liabilities.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or detect fraud. Consequently, investors could lose confidence in our financial reporting and this may decrease the trading price of our stock.

We must maintain effective internal controls to provide reliable financial reports and detect fraud. We have been assessing our internal controls to identify areas that need improvement. We are in the process of implementing changes to internal controls, but have not yet completed implementing these changes. Failure to implement these changes to our internal controls or any others that we identify as necessary to maintain an effective system of internal controls could harm our operating results and cause investors to lose confidence in our reported financial information. Any such loss of confidence would have a negative effect on the trading price of our common stock.

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 timing of IDE approval, 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.

In the future, we may issue additional authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of our present stockholders. We may also issue additional shares of our common stock or other securities that are convertible into or exercisable for common stock in connection with hiring or retaining employees, future acquisitions, future sales of our securities for capital raising purposes, or for other business purposes. 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.

Our common stock is controlled by insiders, who could have significant influence over the outcome of corporate actions requiring board and stockholder approval.

Our officers and directors beneficially own approximately 28.2% of our outstanding shares of common stock. With such concentrated control, these insiders could have influence over the outcome of corporate actions requiring board and stockholder approval, including the election of directors or any other significant corporate transaction. Investors who acquire common stock may have no effective voice in the management of the Company.

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

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. The Company currently has 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 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.

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.

Certain of our outstanding warrants may be redeemed on short notice, which may have an adverse effect on the price of our common stock.

We may redeem certain of our outstanding warrants on 30 days' notice at any time after the date on which the last reported sale price per share of our common stock as reported by the principal exchange or trading facility on which our common stock trades equals or exceeds $2.80 for twenty consecutive trading days. If we give notice of redemption, holders of these warrants will be forced to sell or exercise the warrants they hold or accept the redemption price. The notice of redemption could come at a time when, under specific circumstances or generally, it is not advisable or possible for holders of these warrants to sell or exercise the warrants they hold.

While certain of our warrants are outstanding, it may be more difficult to raise additional equity capital.

While certain of our warrants are outstanding, the holders of those warrants are given the opportunity to profit from a rise in the market price of our common stock. In addition, some outstanding warrants are not redeemable by us. We may find it more difficult to raise additional equity capital while these warrants are outstanding. At any time during which these warrants are likely to be exercised, we may be able to obtain additional equity capital on more favorable terms from other sources.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

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

On November 29, 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.

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. In our complaint, we are seeking money damages for breach of contract, breach of implied covenant of good faith and fair dealing, misrepresentation, fraudulent inducement, unjust enrichment, and violations of M.G.L. c. 93A. The lawsuit involves the terms of the lease agreement for the new headquarters at One Kendall Square. We contend that we are owed an additional period of free rent, pursuant to the agreement. The lawsuit is still in its early stages and no judgments or rulings are pending. We are seeking $650,000 in damages. We estimate legal fees will be between $100,000 and $150,000 and under the terms of the lease agreement the prevailing party in a lawsuit is entitled to reimbursement of its legal fees. We do not currently believe that the pending lawsuit would have a material impact on the financial condition of the Company.

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 and services infringe upon the intellectual property rights of third parties.

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, 2011	$ 3.10	$ 0.60
September 30, 2011	$ 1.20	$ 0.60
June 30, 2011	$ 1.10	$ 0.60
March 31, 2011	$ 2.26	$ 0.75

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

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 6, 2013, the closing bid price of our Common Stock as reported by the OTC Bulletin Board was $2.32 per share.

Trades in the Common Stock may be subject to Rule 15g-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 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 6, 2013, 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

On April 18, 2012, the Company issued 15,000 unregistered shares of Common Stock with a fair market value of approximately $25,000 to an investor relations firm in exchange for services provided. The issuance was made in reliance upon available exemptions from the registration requirements of the Securities Act of 1933, including Section 4(2) thereof and Regulation D thereunder, as well as comparable exemptions under applicable state securities laws.

Item 6. SELECTED FINANCIAL DATA

Not required.

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of financial condition and results of operations should be read in conjunction with our consolidated financial statements and accompanying notes included in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under "Risk Factors," and "Special Note Regarding Forward-Looking Statements",

Management's Discussion and Analysis of Financial Condition and Results of Operations

The following management's discussion and analysis should be read in conjunction with our historical consolidated financial statements and the related notes. The management's discussion and analysis contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Any statements that are not statements of historical fact are forward-looking statements. When used, the words "believe," "plan," "intend," "anticipate," "target," "estimate," "expect" and the like, and/or future tense or conditional constructions ("will," "may," "could," "should," etc.), or similar expressions, identify certain of these forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements in this Annual Report. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors. We do not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Annual Report.

The discussion and analysis of our financial condition and results of operations are based on the Company's financial statements, which management has prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base estimates on historical experience and on various other factors that management believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

As the result of the October 2010 merger with InVivo Therapeutics Corporation and related transactions, InVivo Therapeutics Corporation was considered the accounting acquirer and therefore the financial results of InVivo Therapeutics Corporation are now considered the financial results of the Company on a historical and going-forward basis.

Critical Accounting Policies and Estimates

Our consolidated financial statements, which appear in Item 8 of this Annual Report on Form 10-K, have been prepared in accordance with accounting principles generally accepted in the United States, which require that the management make certain assumptions and estimates and, in connection therewith, adopt certain accounting policies. Our significant accounting policies are set forth in Note 2 to our consolidated financial statements. Of those policies, we believe that the policies discussed below may involve a higher degree of judgment and may be more critical to an accurate reflection of our financial condition and results of operations.

Share-Based Compensation

Stock options are generally granted with an exercise price at fair market value at the date of the grant. The stock options generally expire ten years from the date of grant. Stock option awards vest upon terms determined by the Company’s Board of Directors.

We recognize compensation costs resulting from the issuance of stock-based awards to employees, non-employees and directors as an expense in the statement of operations over the service period based on a measurement of fair value for each stock-based award. The fair value of each option grant was estimated as of the date of grant using the Black-Scholes option-pricing model. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period. Due to our limited operating history and limited number of sales of our Common Stock, we estimated our volatility in consideration of a number of factors including the volatility of our stock as well as that of comparable public companies. We use historical data, as well as subsequent events occurring prior to the issuance of the consolidated financial statements, to estimate option exercise and employee termination within the valuation model. The expected term of options granted under the Company’s stock plans is based on the average of the contractual term (generally 10 years) and the vesting period (generally 48 months) The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option.

The following assumptions were used to estimate the fair value of stock options granted using the Black-Scholes option pricing model:

	December 31,	
	2012	2011
Risk-free interest rate	0.62-3.05%	0.97-3.05%
Expected dividend yield	0%	0%
Expected term (employee grants)	6.25	6.25
Expected volatility	75%	49%

Derivative Instruments

Certain of our issued and outstanding warrants to purchase Common Stock contain anti-dilution provisions. These warrants do not meet the requirements for classification as equity and are recorded as derivative warrant liabilities. We use valuation methods and assumptions that consider among other factors the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates consistent with those discussed in Share-Based Compensation above in estimating the fair value for the warrants considered to be derivative warrant liabilities. Such derivative warrant liabilities are initially recorded at fair value with subsequent changes in fair value charged (credited) to operations in each reporting period. The fair value of the derivative warrant liability is most sensitive to changes in the fair value of the underlying Common Stock and the estimated volatility of our Common Stock.

Research and Development and General and Administrative Expenses

Research and development expenses consist primarily of payroll and payments to contract research and development companies and payroll. General and administrative expenses consist primarily of payroll, rent and professional services.

Results of Operations

Comparison of the years ended December 31, 2012 and 2011

Research and Development Expenses

Research and development expenses increased by $2,273,000 to approximately $6,376,000 for the year ended December 31, 2012 from approximately $4,103,000 for the year ended December 31, 2011. The increase in expenses is primarily attributable to increased research and development activity and the resulting increase in compensation costs of $1,245,000 due to both additional staffing and pay raises, $765,000 of costs in 2012 for the manufacturing of scaffolding devices, increase in rent and facility costs of $609,000, and increase in lab supplies of $212,000, offset by a reduction in pre-clinical testing of $861,000.

General and Administrative Expenses

General and administrative expenses increased by $1,848,000 to approximately $6,404,000 for the year ended December 31, 2012 from approximately $4,556,000 for the year ended December 31, 2011. The increase in expenses is primarily attributable to an increase in compensation costs of $534,000 due to additional staffing and pay raises, an increase of $178,000 in legal costs, an increase of $238,000 in recruiting and relocation costs, an increase of $170,000 in travel and conference meeting costs, an increase of $455,000 in stock compensation costs and an increase in rent and facilities costs of $240,000.

Interest Expense

Interest expense increased by $59,000 to approximately $72,000 for the year ended December 31, 2012 from approximately $13,000 for the year ended December 31, 2011. The increase in interest expense is due to an increase in borrowing under the loans payable.

Derivatives Gain (Loss)

Derivatives gain (loss) increased by approximately $43,546,000 to a derivative gain of $17,480,000 for the year ended December 31, 2012 from a derivative loss of $26,066,000 for the year ended December 31, 2011. The increase in this non-cash gain for the year ended December 31, 2012 reflects the decrease in the fair value of derivative warrant liability due primarily to the decrease in the fair value of the underlying Common Stock.

Financial Condition, Liquidity and Capital Resources

Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. Accordingly, the Company is considered to be in the development stage.

Since inception, the Company incurred negative cash flows from operations. The Company has financed its operations primarily through the sale of equity-related securities. At December 31, 2012, the accumulated deficit was $43,153,000 and the stockholders' deficit was $2,310,000.

At December 31, 2012, we had total current assets of $13,570,000 and current liabilities of $16,791,000 resulting in a working capital deficit of $3,221,000. At December 31, 2012, the Company had total assets of $16,062,000 and total liabilities of $18,372,000, resulting in a stockholders' deficit of $2,310,000.

Net cash used by operating activities for the year ended December 31, 2012 was approximately $10,204,000. The operating loss used $12,678,000, increases in accounts payable and accrued expenses provided $988,000, non-cash stock share based compensation provided $1,233,000 and depreciation and amortization provided $367,000.

Net cash used by investing activities for the year ended totaled $2,141,000 for purchases of capital equipment.

Net cash provided by financing activities was approximately $20,806,000 for the year ended December 31, 2012, due mainly to approximately $18,155,000 proceeds from a public offering. In addition, the Company received $1,241,000 from the exercise of stock options and warrants and approximately $1,444,000 from loans, net of repayments.

At December 31, 2012, the Company had cash of approximately $12,825,000 which the Company expects to be sufficient to meet its operating and capital requirements into the first quarter of 2014. However, the Company will need to raise substantial additional capital in the future to complete clinical trials, obtain marketing approvals and commercialize its products, potentially through debt or equity financings. The sale of debt or equity securities may cause dilution to existing stockholders. Furthermore, there can be no assurance that we will be able to raise such funds if and when they are required. Failure to obtain future funding when needed or on acceptable terms would materially adversely affect our results of operations.

Off Balance Sheet Arrangements

We have no off balance sheet arrangements that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources.

Commitments and Contingencies

On November 29, 2011, and as amended on September 17, 2012, the Company entered into a commercial lease for 26,150 square feet of office, laboratory and manufacturing space in Cambridge, Massachusetts ("Cambridge Lease"). The term of this lease is six years and three months, with one five-year extension option. The terms of the lease requires a standby letter of credit in the amount of $311,000 secured by a deposit with a commercial bank.

Pursuant to the terms of the non-cancelable lease agreements in effect at December 31, 2012, future minimum rent commitments are as follows:

Year Ending December 31,	
2013	$1,168,659
2014	1,198,265
2015	1,237,533
2016	1,263,642
2017	1,294,859
2018	1,045,752
Total	$7,208,710

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required.

Item 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Consolidated Financial Statements

Table of Contents

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of InVivo Therapeutics Holdings Corp.:

We have audited the accompanying consolidated balance sheets of InVivo Therapeutics Holdings Corp. as of December 31, 2012 and 2011, and the related consolidated statements of operations, changes stockholders' deficit and cash flows for the years then ended and for the period from November 28, 2005 (inception) to December 31, 2012 . These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of InVivo Therapeutics Holdings Corp. as of December 31, 2012 and 2011, and the results of its operations and its cash flows for the periods then ended, in conformity with U.S. generally accepted accounting principles.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), InVivo Therapeutics Holdings Corp.'s internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 11, 2013 expressed an unqualified opinion on the effectiveness of InVivo Therapeutics Holdings Corp.'s internal control over financial reporting.

/s/ Wolf & Company, P.C.

Boston, Massachusetts
March 11, 2013

Table of Contents

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

	December 31, 2012	December 31, 2011
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 12,825,090	$ 4,363,712
Restricted cash	601,351	547,883
Prepaid expenses and other current assets	143,867	104,022
Total current assets	13,570,308	5,015,617
Property and equipment, net	2,311,942	520,482
Other assets	179,415	166,139
Total assets	$ 16,061,665	$ 5,702,238
LIABILITIES AND STOCKHOLDERS' DEFICIT:		
Current liabilities:		
Accounts payable	$ 1,152,550	$ 567,195
Loan payable-current portion	—	50,578
Capital lease payable-current portion	32,606	30,724
Derivative warrant liability	14,584,818	35,473,230
Accrued expenses	1,021,275	618,369
Total current liabilities	16,791,249	36,740,096
Loan payable-less current portion	1,578,000	83,794
Capital lease payable-less current portion	2,799	38,042
Total liabilities	18,372,048	36,861,932
Commitments and contingencies		
Stockholders' deficit:		
Common stock, $0.00001 par value, authorized 200,000,000 shares; issued and outstanding 65,881,122 and 53,760,471 shares at December 31 2012 and 2011, respectively	659	538
Additional paid-in capital	40,842,339	16,656,830
Deficit accumulated during the development stage	(43,153,381)	(47,817,062)
Total stockholders' deficit	(2,310,383)	(31,159,694)
Total liabilities and stockholders' deficit	$ 16,061,665	$ 5,702,238

See notes to consolidated financial statements.

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Consolidated Statements of Operations

	Years Ended December 31, 2012	Years Ended December 31, 2011	Period from November 28, 2005 (inception) to December 31, 2012
Operating expenses:			
Research and development	$ 6,375,795	$ 4,102,847	$ 15,259,629
General and administrative	6,403,656	4,555,872	14,655,193
Total operating expenses	12,779,451	8,658,719	29,914,822
Operating loss	(12,779,451)	(8,658,719)	(29,914,822)
Other income (expense):			
Other income	—	—	383,000
Interest income	35,184	8,759	55,233
Interest expense	(71,726)	(12,676)	(1,138,057)
Derivatives gain (loss)	17,479,674	(26,065,579)	(12,538,487)
Other income (expense), net	17,443,132	(26,069,496)	(13,238,311)
Net income (loss)	$ 4,663,681	$(34,728,215)	$(43,153,133)
Net income (loss) per share, basic	$ 0.07	$ (0.67)	$ (1.22)
Net income (loss) per share, diluted	$ 0.06	$ (0.67)	$ (1.22)
Weighted average number of common shares outstanding, basic	63,226,899	51,894,871	35,348,456
Weighted average number of common shares outstanding, diluted	71,919,419	51,894,871	35,348,456

See notes to the consolidated financial statements.

InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Consolidated Statements of Changes in Stockholders' Deficit

	Common Stock			Deficit Accumulated During the Development	Total Stockholders'
	Shares	Amount	Additional Paid-in Capital	Stage	Deficit
Balance on inception date, November 28, 2005	—	$ —	$ —	$ —	$ —
Issuance of founders stock	24,787,080	248	—	(248)	—
Share-based compensation expense	—	—	18,347	—	18,347
Net loss	—	—	—	(1,097,702)	(1,097,702)
Balance as of December 31, 2007	24,787,080	248	18,347	(1,097,950)	(1,079,355)
Share-based compensation expense	—	—	24,526	—	24,526
Net loss	—	—	—	(1,564,069)	(1,564,069)
Balance as of December 31, 2008	24,787,080	248	42,873	(2,662,019)	(2,618,898)
Share-based compensation expense	—	—	171,059	—	171,059
Conversion of convertible notes payable and accrued interest	1,472,435	15	1,344,351	—	1,344,366
Net loss	—	—	—	(2,515,878)	(2,515,878)
Balance as of December 31, 2009	26,259,515	263	1,558,283	(5,177,897)	(3,619,351)
Share-based compensation expense	—	—	664,908	—	664,908
Issuance of common stock in March 2010	1,095,258	10	999,990	—	1,000,000
Conversion of convertible notes payable and accrued interest	3,792,417	38	3,328,090	—	3,328,128
Issuance of common stock in reverse merger	6,999,981	70	(70)	—	—
Beneficial conversion feature on notes payable	—	—	272,762	—	272,762
Issuance of common stock in private placement, net of stock issuance costs of $2,072,117 and non stock issuance costs of $5,369,570	12,995,403	130	3,907,274	—	3,907,404
Conversion of convertible bridge notes in conjunction with the private placement	504,597	5	504,592	—	504,597
Net loss	—	—	—	(7,910,950)	(7,910,950)
Balance as of December 31, 2010	51,647,171	516	11,235,829	(13,088,847)	(1,852,502)
Share-based compensation expense	—	—	921,512	—	921,512
Issuance of common stock in private placement	980,392	10	1,999,990	—	2,000,000
Issuance of common stock for services	215,000	2	209,448	—	209,450
Issuance of common stock upon exercise of warrants	734,329	7	988,367	—	988,374
Issuance of common stock upon exercise of stock options	143,731	2	10,433	—	10,435
Issuance of common stock to 401(k) plan	39,848	1	41,661	—	41,662
Fair value of warrants issued for services	—	—	10,051	—	10,051
Fair value of derivative warrant liability reclassified to additional paid-in capital	—	—	1,239,539	—	1,239,539
Net loss	—	—	—	(34,728,215)	(34,728,215)
Balance as of December 31, 2011	53,760,471	538	16,656,830	(47,817,062)	(31,159,694)
Share-based compensation expense	—	—	1,232,959	—	1,232,959
Issuance of common stock in public offering	9,523,810	95	18,154,948	—	18,155,043
Issuance of common stock for services	15,000	—	24,750	—	24,750
Issuance of common stock upon exercise of warrants	1,779,716	18	1,129,077	—	1,129,095
Issuance of common stock upon exercise of stock options	755,020	8	111,597	—	111,605
Issuance of common stock to 401(k) plan	47,105	—	91,524	—	91,524
Fair value of warrants issued for services	—	—	31,916	—	31,916
Fair value of derivative warrant liability reclassified to additional paid-in capital	—	—	3,408,738	—	3,408,738
Net income	—	—	—	4,663,681	4,663,681
Balance as of December 31, 2012	65,881,122	$ 659	$40,842,339	$(43,153,381)	$ (2,310,383)

See notes to the consolidated financial statements.

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Consolidated Statements of Cash Flows

	Years Ended December 31,		Period from November 28, 2005 (inception) to December 31,
	2012	2011	2012
Cash flows from operating activities:			
Net income (loss)	$ 4,663,681	$(34,728,215)	$ (43,153,133)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization expense	366,893	144,662	604,520
Non-cash derivative (gain) losses	(17,479,674)	26,065,579	12,538,487
Non-cash interest expense	21,870	—	984,704
Common stock issued to 401(k) plan	91,524	41,662	133,186
Common stock issued for services	24,750	209,451	234,201
Share-based compensation expense	1,232,959	921,512	3,033,311
Changes in operating assets and liabilities:			—
Restricted cash	(53,468)	(547,883)	(601,351)
Prepaid expenses and other current assets	(60,575)	(12,805)	(154,546)
Other assets	—	(125,000)	(200,000)
Accounts payable	585,355	230,250	1,152,550
Accrued interest payable	—	—	(15,256)
Accrued expenses	402,906	370,822	1,021,275
Net cash used in operating activities	(10,203,779)	(7,429,965)	(24,422,052)
Cash flows from investing activities:			
Purchases of property and equipment	(2,140,853)	(278,923)	(2,771,561)
Net cash used in investing activities	(2,140,853)	(278,923)	(2,771,561)
Cash flows from financing activities:			
Proceeds from issuance of convertible notes payable	—	—	4,181,000
Proceeds from convertible bridge notes	—	—	500,000
Principal payments on capital lease obligation	(33,361)	(24,774)	(58,135)
Proceeds from loans payable	1,747,000	151,733	1,898,733
Repayment of loans payable	(303,372)	(17,361)	(320,733)
Proceeds from issuance of common stock and warrants	19,395,743	2,998,808	33,817,838
Net cash provided by financing activities	20,806,010	3,108,406	40,018,703
Increase (Decrease) in cash and cash equivalents	8,461,378	(4,600,482)	12,825,090
Cash and cash equivalents at beginning of period	4,363,712	8,964,194	—
Cash and cash equivalents at end of period	$ 12,825,090	$ 4,363,712	$ 12,825,090
Supplemental disclosure of cash flow information and non-cash transactions:			
Cash paid for interest	$ 49,862	$ 8,530	$ 155,909
Conversion of convertible notes payable and accrued interest into common stock	$ —	$ —	$ 4,672,484
Conversion of convertible bridge note payable and accrued interest into common stock	$ —	$ —	$ 504,597
Asset acquired through capital lease obligation	$ —	$ 93,540	$ 93,540
Beneficial conversion feature on convertible and bridge notes payable	$ —	$ —	$ 134,410
Fair value of warrants issued with bridge notes payable	$ —	$ —	$ 178,726
Fair value of warrants issued in connection with loan agreement	$ 31,916	$ 10,051	$ 41,967
Issuance of founders shares	$ —	$ —	$ 248
Reclassification of derivative warrant liability to additional paid-in capital	$ 3,408,738	$ 1,239,539	$ 4,648,277

See notes to the consolidated financial statements.

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements

Years Ended December 31, 2012 and 2011, and the Period from
November 28, 2005 (Inception) through December 31, 2012

1. NATURE OF OPERATIONS

Business

InVivo Therapeutics Corporation ("InVivo") was incorporated on November 28, 2005 under the laws of the State of Delaware. InVivo is developing and commercializing biopolymer scaffolding devices for the treatment of spinal cord injuries, peripheral nerve injuries and other neurotrauma conditions. In spinal cord injuries, the biopolymer devices are designed to protect the damaged spinal cord from further secondary injury and promote neuroplasticity, a process where functional recovery can occur through the rerouting of signaling pathways to the spared healthy tissue.

Since its inception, InVivo has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. Accordingly, InVivo is considered to be in the development stage.

Reverse Merger

On October 26, 2010 InVivo completed a reverse merger transaction (the "Merger") with InVivo Therapeutics Holdings Corp. (formerly Design Source, Inc.) ("ITHC"), a publicly traded company incorporated under the laws of the State of Nevada. InVivo became a wholly owned subsidiary of ITHC, which continues to operate the business of InVivo. As part of the Merger, ITHC issued 31,147,190 shares of its Common Stock to the holders of InVivo common stock on October 26, 2010 in exchange for the 2,261,862 outstanding common shares of InVivo and also issued 500,000 shares to its legal counsel in consideration for legal services provided. All share and per share amounts presented in these consolidated financial statements have been retroactively restated to reflect the 13.7706 to 1 exchange ratio of InVivo shares for ITHC shares in the Merger. Immediately prior to the Merger, ITHC had 6,999,981 shares of Common Stock outstanding.

The Merger was accounted for as a "reverse merger," and InVivo is deemed to be the accounting acquirer. The Merger was recorded as a reverse recapitalization, equivalent to the issuance of common stock by InVivo for the net monetary assets of ITHC accompanied by a recapitalization. At the date of the Merger, the 6,999,981 outstanding ITHC shares were reflected as an issuance of InVivo common stock to the prior shareholders of ITHC. ITHC had no net monetary assets as of the Merger so this issuance was recorded as a reclassification between additional paid-in capital and par value of Common Stock.

The historical consolidated financial statements are those of InVivo as the accounting acquirer. The post-merger combination of ITHC and InVivo is referred to throughout these notes to consolidated financial statements as the "Company." Subsequent to the Merger, the Company completed three closings as part of a private placement.

On October 26, 2010, in connection with the Merger described above, ITHC transferred all of its operating assets and liabilities to its wholly-owned subsidiary, D Source Split Corp., a company organized under the laws of Nevada ("DSSC"). DSSC was then split-off from ITHC through the sale of all outstanding shares of DSSC (the "Split-Off"). The assets and liabilities of ITHC were transferred to the Split-Off Shareholders in the Split-Off. ITHC executed a split off agreement with the Split-Off Shareholders which obligates the Split-Off Shareholders to assume all prior liabilities associated with Design Source, Inc. and all DSSC liabilities. In conjunction with the Split-Off, certain shareholders of ITHC surrendered for cancellation shares of ITHC common stock for no additional consideration. The purpose of the Split-Off was to make

NATURE OF OPERATIONS (continued)

ITHC a shell company with no assets or liabilities in order to facilitate the Merger. Although all transactions related to the Merger occurred simultaneously, the Split-Off, including the cancellation of shares, was considered to have occurred immediately prior to the Merger for accounting purposes. As the accounting acquiree in a reverse merger with a shell company, the historical financial statements of ITHC are not presented and these ITHC transactions are not reflected in the Company's accompanying consolidated financial statements.

2. SIGNIFICANT ACCOUNTING POLICIES

A summary of the significant accounting policies followed by the Company in the preparation of the financial statements is as follows:

Use of estimates

The process of preparing financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of assets and liabilities at the date of financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates and changes in estimates may occur.

Principles of consolidation

The consolidated financial statements include the accounts of InVivo Therapeutics Holdings Corp. and its wholly-owned subsidiary, InVivo Therapeutics Corporation. All significant intercompany balances and transactions have been eliminated in consolidation.

Cash and cash equivalents

The Company considers only those investments which are highly liquid, readily convertible to cash, and that mature within three months from date of purchase to be cash equivalents. Marketable investments are those with original maturities in excess of three months.

At December 31, 2012 and 2011, cash equivalents were comprised of money market funds. The Company had no marketable investments at December 31, 2012 and 2011.

Cash and cash equivalents consist of the following:

	December 31,	
	2012	2011
Cash on hand	$ 209,380	$ 133,035
Money market fund	12,615,710	4,230,677
Total cash and cash equivalents	$12,825,090	$4,363,712

Restricted cash

Restricted cash of $601,000 represents a $290,000 security deposit related to the Company's credit card account, and a $311,000 standby letter of credit in favor of a landlord (see Note 16).

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

SIGNIFICANT ACCOUNTING POLICIES (continued)

Financial instruments

The carrying amounts reported in the consolidated balance sheet for cash and cash equivalents and accounts payable approximate fair value based on the short-term nature of these instruments. The carrying value of loans payable approximate their fair value due to the market terms.

Property and equipment

Property and equipment are carried at cost. Depreciation expense is provided over the estimated useful lives of the assets using the straight-line method. A summary of the estimated useful lives is as follows:

Classification	Estimated Useful Life
Computer hardware	5 years
Software	3 years
Office furniture and equipment	5 years
Research and lab equipment	5 years
Leasehold improvements	6.25 years

Depreciation expense for the years ended December 31, 2012 and 2011 was $349,393 and $132,162, respectively. Maintenance and repairs are charged to expense as incurred, while any additions or improvements are capitalized.

Research and development expenses

Costs incurred for research and development are expensed as incurred.

Concentrations of credit risk

The Company has no significant off-balance-sheet concentration of credit risk such as foreign exchange contracts, option contracts or other hedging arrangements. The Company may from time to time have cash in banks in excess of FDIC insurance limits.

Segment information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and manages its business as principally one operating segment, which is developing and commercializing biopolymer scaffolding devices for the treatment of spinal cord injuries. As of December 31, 2012 and 2011, all of the Company’s assets were located in the United States.

Income taxes

For federal and state income taxes, deferred tax assets and liabilities are recognized based upon temporary differences between the financial statement and the tax basis of assets and liabilities. Deferred income taxes are based upon prescribed rates and enacted laws applicable to periods in which differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that some portion or all of the

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

SIGNIFICANT ACCOUNTING POLICIES (continued)

deferred tax assets will not be realized. Accordingly, the Company provides a valuation allowance, if necessary, to reduce deferred tax assets to amounts that are realizable. Tax positions taken or expected to be taken in the course of preparing the Company's tax returns are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authority.

Tax positions not deemed to meet a more-likely-than-not threshold would be recorded as a tax expense in the current year. There were no uncertain tax positions that require accrual or disclosure to the financial statements as of December 31, 2012 or 2011. Tax years subsequent to 2008 remain open to examination by U.S. federal and state tax authorities.

Impairment of long-lived assets

The Company continually monitors events and changes in circumstances that could indicate that carrying amounts of long-lived assets may not be recoverable. An impairment loss is recognized when expected cash flows are less than an asset's carrying value. Accordingly, when indicators of impairment are present, the Company evaluates the carrying value of such assets in relation to the operating performance and future undiscounted cash flows of the underlying assets. The Company's policy is to record an impairment loss when it is determined that the carrying value of the asset may not be recoverable. No impairment charges were recorded for the years ended December 31, 2012 and 2011.

Share-based payments

The Company recognizes compensation costs resulting from the issuance of stock-based awards to employees, non-employees and directors as an expense in the statement of operations over the service period based on a measurement of fair value for each stock-based award. The fair value of each option grant is estimated as of the date of grant using the Black-Scholes option-pricing model. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period. Due to its limited operating history, limited number of sales of its Common Stock and limited history of its shares being publicly traded, the Company estimates its volatility in consideration of a number of factors including the volatility of comparable public companies.

Derivative instruments

The Company generally does not use derivative instruments to hedge exposures to cash-flow or market risks; however, certain warrants to purchase Common Stock that do not meet the requirements for classification as equity are classified as liabilities. In such instances, net-cash settlement is assumed for financial reporting purposes, even when the terms of the underlying contracts do not provide for a net-cash settlement. Such financial instruments are initially recorded at fair value with subsequent changes in fair value charged (credited) to operations in each reporting period. If these instruments subsequently meet the requirements for classification as equity, the Company reclassifies the fair value to equity.

Net income (loss) per common share

Basic net income (loss) per share of Common Stock has been computed by dividing net income (loss) by the weighted average number of shares outstanding during the period. Diluted net income per share of Common Stock has been computed by dividing net income by the weighted average number of shares outstanding

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

SIGNIFICANT ACCOUNTING POLICIES (continued)

plus the dilutive effect, if any, of outstanding stock options, warrants and convertible securities. Diluted net loss per share of Common Stock has been computed by dividing the net loss for the period by the weighted average number of shares of Common Stock outstanding during such period. In a net loss period, options, warrants and convertible securities are anti-dilutive and therefore excluded from diluted loss per share calculations.

Recent Accounting Pronouncements

In July 2012, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2012-02, Testing Indefinite-Lived Intangible Assets for Impairment, which gives companies the option to perform a qualitative assessment to determine whether it is more likely than not that an indefinite-lived intangible asset is impaired. If a company determines that it is more likely than not that the fair value of such an asset exceeds its carrying amount, it would not need to calculate the fair value of the asset in that year. However, if a company concludes otherwise, it must calculate the fair value of the asset, compare that value with its carrying amount and record an impairment charge, if any. The amendments in the ASU are effective for annual and interim indefinite-lived intangible asset impairment tests performed for fiscal years beginning after September 15, 2012, which is fiscal 2013 for the Company. Early adoption is permitted. The Company is currently assessing its adoption plans.

In December 2011, the FASB issued an ASU 2011-11, Disclosures about Offsetting Assets and Liabilities (Topic 210), that provides amendments for disclosures about offsetting assets and liabilities. The amendments require an entity to disclose information about offsetting and related arrangements to enable users of its financial statements to understand the effect of those arrangements on its financial position. Entities are required to disclose both gross information and net information about both instruments and transactions eligible for offset in the statement of financial position and instruments and transactions subject to an agreement similar to a master netting arrangement. This scope would include derivatives, sale and repurchase agreements and reverse sale and repurchase agreements, and securities borrowing and securities lending arrangements. The amendments are effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods. Disclosures required by the amendments should be provided retrospectively for all comparative periods presented. For the Company, the amendment is effective for fiscal year 2013. The Company is currently evaluating the impact these amendments may have on its disclosures.

3. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	December 31, 2012	December 31, 2011
Computer software and hardware	$ 362,352	$ 138,662
Research and lab equipment	1,448,226	585,586
Leasehold improvements	298,222	
Office Equipment	756,301	—
Less accumulated depreciation and amortization	(553,159)	(203,766)
Net	$2,311,942	$ 520,482

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

4. OTHER ASSETS

Other assets consist of patent licensing fees paid to license intellectual property (see Note 15). The Company is amortizing the license fee to research and development over its 15-year term.

	December 31, 2012	December 31, 2011
Patent licensing fee	$200,000	$200,000
Accumulated amortization	(51,361)	(33,861)
	$148,639	$166,139

Amortization expense was $17,500 and $12,500 for the years ended December 31, 2012 and 2011, respectively. Amortization expense in each of the next five years is expected to be approximately $17,000 per year.

5. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	December 31, 2012	December 31, 2011
Other accrued expenses	$ 486,603	$115,102
Accrued payroll	224,596	358,144
Deferred rent payable	310,076	—
Accrued vacation	—	145,123
	$1,021,275	$618,369

6. FAIR VALUES OF ASSETS AND LIABILITIES

The Company groups its assets and liabilities generally measured at fair value in three levels, based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value.

Level 1 – Valuation is based on quoted prices in active markets for identical assets or liabilities. Level 1 assets and liabilities generally include debt and equity securities that are traded in an active exchange market. Valuations are obtained from readily available pricing sources for market transactions involving identical assets or liabilities.

Level 2 – Valuation is based on observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Valuation is based on unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation.

The Company uses valuation methods and assumptions that consider among other factors the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants considered to be derivative instruments.

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)
Notes to Consolidated Financial Statements (Continued)

FAIR VALUES OF ASSETS AND LIABILITIES (continued)

Assets and liabilities measured at fair value on a recurring basis are summarized below:

	December 31, 2012			
	Level 1	Level 2	Level 3	Fair Value
Liabilities:				
Derivative warrant liability	$ —	$14,584,818	$ —	$14,584,818

	December 31, 2011			
	Level 1	Level 2	Level 3	Fair Value
Liabilities:				
Derivative warrant liability	$ —	$35,473,230	$ —	$35,473,230

7. CAPITAL LEASE PAYABLE

In February 2011, the Company entered into a capital lease agreement under which the Company leased certain laboratory equipment. Capital lease obligation consisted of the following:

	December 31,	
	2012	2011
Capital lease payable	$ 35,405	$ 68,766
Less: current portion	(32,606)	(30,724)
	$ 2,799	$ 38,042

The total value of the laboratory equipment acquired under this capital lease agreement was $124,151 including a down payment of approximately $31,000. The capital lease is payable in monthly installments of $2,812 payable over thirty six months with the final payment due in January 2014. For the years ended December 31, 2012 and 2011, interest expense recorded on the capital lease was $3,189 and $3,987, respectively. For the years ended December 31, 2012 and 2011, depreciation expense on the assets under capital lease was $24,831 and $22,761, respectively. The net book value at December 31, 2012 and 2011, amounted to $76,559 and $101,390, respectively.

8. LOAN PAYABLE

In October 2012, the Company entered into a loan agreement with the Massachusetts Development Finance Agency (“MassDev”) from the Commonwealth of Massachusetts’s Emerging Technology fund. The loan agreement provides the Company with a $2,000,000 line of credit, with $200,000 to be used for working capital purposes and the remainder of which is to be used for the purchase of capital equipment. The annual interest rate is fixed at 6.5% with interest payments only commencing on November 1, 2012 for the first thirty months and then equal interest and principal payments over the next fifty-four months with the final maturity on October 5, 2019. Based on the $1,578,000 balance outstanding as of December 31, 2012, equal monthly principal payments of $29,222 will be due commencing on May 1, 2015. Therefore, for the years ending December 31, 2015, 2016, 2017 and thereafter, principal payments of approximately $234,000, $351,000, $351,000 and $642,000, respectively, will be due In September 2012, the Company was assessed commitment fees totaling $15,000, which was charged to interest expense. In October 2012 as part of the commitment fee, the Company issued MassDev a warrant for the purchase of 36,145 shares of Common Stock. The warrant has a seven year term and is exercisable at $1.66 per share. The fair value of the warrant

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

LOAN PAYABLE (continued)

was determined to be $31,916 and was recorded as a deferred financing cost and is being amortized to interest expense over a seven year period commencing in October 2012. Amortization of the deferred financing cost for the year ended December 31, 2012 was $1,140 and was included in interest expense. The equipment line of credit is secured by substantially all the assets of the Company excluding intellectual property. In the fourth quarter of 2012, the Company drew on the line and received proceeds of $1,578,000, including $200,000 for working capital purposes and $1,378,000 for capital equipment. Interest expense related to this loan was $14,794 for the year ended December 31, 2012.

In June 2011, the Company entered into a loan agreement with a bank. The loan agreement had provided the Company with a $1,000,000 line of credit for the purchase of capital equipment. The annual interest rate was the greater of 6.75% or 3.50% above the Prime Rate. Borrowings were repayable in equal monthly installments over a thirty six month period. The Company was assessed commitment fees totaling $10,000 and issued the bank a warrant for the purchase of 16,071 shares of Common Stock. The warrant has a seven year term and is exercisable at $1.40 per share. The fair value of the warrant was determined to be approximately $10,000 and was recorded as a deferred financing cost that was being amortized to interest expense over the life of the loan. Under the terms of the MassDev loan disclosed above, in October 2012 the Company repaid the outstanding balance of $134,372 due to the bank and wrote off the remaining deferred financing costs. Amortization of deferred interest on this loan for the years ended December 31, 2012 and 2011 was $6,219 and $4,146, respectively, and was included in interest expense Interest expense related to the loan payable to the bank was $16,428 and $8,334 for the years ended December 31, 2012 and 2011, respectively.

At December 31, loans payable consist of the following:

	December 31, 2012	December 31, 2011
Equipment Loan	$1,578,000	$134,372
Less: current portion	—	(50,578)
	$1,578,000	$ 83,794

9. INCOME TAXES

No provision or benefit for federal or state income taxes has been recorded, as the Company has incurred a net loss for all of the periods presented, and the Company has provided a full valuation allowance against its deferred tax assets.

At December 31, 2012, the Company had Federal and Massachusetts net operating loss carryforwards of approximately $26,533,000 and $23,328,000, respectively, of which federal carryforwards will expire in varying amounts beginning in 2026. Massachusetts net operating losses began to expire in 2011. Utilization of net operating losses may be subject to substantial annual limitations due to the “change in ownership” provisions of the Internal Revenue Code, and similar state provisions. The annual limitations may result in the expiration of net operating losses before utilization. The Company also had research and development tax credit carryforwards at December 31, 2012 of approximately $258,000 which will begin to expire in 2021 unless previously utilized.

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)
Notes to Consolidated Financial Statements (Continued)

INCOME TAXES (continued)

Significant components of the Company's net deferred tax asset are as follows:

	December 31, 2012	December 31, 2011
Net operating loss carryforward	$ 10,329,617	$ 5,896,441
Research and development credit carryforward	329,584	257,110
Stock-based compensation	1,090,746	740,714
Depreciation and amortization	(81,305)	—
Charitable contributions	72,693	68,694
Subtotal	11,741,335	6,962,959
Valuation allowance	(11,741,335)	(6,962,959)
Net deferred taxes	$ —	$ —

The Company has maintained a full valuation allowance against its deferred tax assets in all periods presented. A valuation allowance is required to be recorded when it is more likely than not that some portion or all of the net deferred tax assets will not be realized. Since the Company cannot be assured of generating taxable income and thereby realizing the net deferred tax assets, a full valuation allowance has been provided. In the years ended December 31, 2012 and 2011, the valuation allowance increased by $4,778,000 and $3,374,000, respectively.

The Company has no uncertain tax positions at December 31, 2012 and 2011 that would affect its effective tax rate. The Company does not anticipate a significant change in the amount of uncertain tax positions over the next twelve months. Since he Company is in a loss carryforward position, the Company is generally subject to US federal and state income tax examinations by tax authorities for all years for which a loss carryforward is available.

Income tax benefits computed using the federal statutory income tax rate differs from the Company's effective tax rate primarily due to the following:

	December 31, 2012	December 31, 2011
Statutory rate	34.0%	34.0%
State taxes, net of benefit	-14.2%	1.4%
Permanent differences:		
Derivative losses	-127.4%	-25.7%
Other	-1.9%	-0.2%
R&D tax credit	7.0%	0.2%
Increase in valuation reserve	102.5%	-9.7%
	0.0%	0.0%

10. COMMON STOCK

The Company has authorized 200,000,000 shares of Common Stock, $0.00001 par value per share, of which 65,881,122, shares were issued and outstanding as of December 31, 2012, and 53,760,471 shares were issued and outstanding as of December 31, 2011.

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

COMMON STOCK (continued)

In February 2012, the Company completed a public offering of Common Stock and issued 9,523,810 shares of Common Stock at a purchase price of $2.10 per common share. The offering raised gross proceeds of approximately $20,000,000 and the Company received net proceeds of $18,155,000 after deducting underwriter discounts and offering expenses.

During the year ended December 31, 2012, the Company issued 755,020 shares of Common Stock upon the exercise of stock options and received cash proceeds of approximately $112,000.

During the year ended December 31, 2012, the Company issued 1,779,716 shares of Common Stock upon the exercise of warrants, including warrants to purchase 1,865,670 shares of Common Stock exercised through cashless exercise provisions and warrants to purchase 852,946 shares of Common Stock exercised for cash, providing cash proceeds of $1,129,000.

During 2012, the Company issued 15,000 unregistered shares with a fair value of approximately $25,000 to an investor relations firm in exchange for services provided.

During the year ended December 31, 2012, the Company issued 47,105 shares of common stock with a fair value of $91,524 to the Company's 401(k) plan as a matching contribution.

In December 2011, the Company completed a private placement with an investor that raised $2,000,000 of net proceeds. In this transaction the Company issued 980,392 shares of unregistered common stock and a warrant to purchase 343,137 shares exercisable at $03.06 per share with a five year term. The warrant was recorded as a debit and credit to additional paid-in capital.

During 2011, the Company issued 143,731 shares of Common Stock upon the exercise of stock options and received cash proceeds of approximately $10,000.

During 2011, the Company issued 215,000 unregistered shares with a fair value of approximately $198,000 to an investor relations firms in exchange for services provided.

In 2011, the Company issued 39,848 shares with a fair value of approximately $42,000 to the Company's 401(k) plan as a matching contribution.

During the fourth quarter of 2011, the Company issued 734,329 shares upon the exercise of warrants and received cash proceeds of approximately $988,000.

Common Stock Reserves

As of December 31, 2012, the Company had the following reserves established for the future issuance of Common Stock as follows:

Reserves for the exercise of warrants	15,723,504
Reserves for the exercise of stock options	10,123,985
Total Reserves	25,847,489

11. DERIVATIVE INSTRUMENTS

Certain warrants outstanding have provisions that include anti-dilution protection and, under certain conditions, grant the right to the holder to request the Company to repurchase the warrant. Accordingly, these warrants are accounted for as derivative liabilities. The Company uses the Black-Scholes option

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

DERIVATIVE INSTRUMENTS (continued)

pricing model and assumptions that consider among other factors the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants considered to be derivative instruments. The fair value of these derivative instruments at December 31, 2012 and 2011 was $14,584,818 and $35,473,230, respectively and is included as a derivative warrant liability, a current liability. Changes in fair value of the derivative financial instruments are recognized currently in the Statement of Operations as a derivatives gain or loss. The warrant derivative gains (losses) are non-cash income (expenses) and for the years ended December 31, 2012 and 2011 $17,479,674 and $(26,065,579) respectively were included in other income (expense) in the consolidated statements of operations.

The assumptions used principally in determining the fair value of warrants were as follows:

	As of December 31,	
	2012	2011
Risk free interest rate	0.32-0.35%	0.52-0.58%
Expected dividend yield	0%	0%
Contractual term	2.7-2.9 years	3.7-3.9 years
Expected volatility	73%	79%

The primary underlying risk exposure pertaining to the warrants is the change in fair value of the underlying Common Stock for each reporting period. The table below presents the changes in derivative warrant liability during the years ended December 31, 2012 and 2011:

	Year Ended December 31,	
	2012	2011
Balance at beginning of year	$ 35,473,230	$10,647,190
Increase (decrease) in the fair value of the warrants	(17,479,674)	26,065,579
Reduction in derivative liability due to exercise of warrants	(3,408,738)	(1,239,539)
Balance at end of year	$ 14,584,818	$35,473,230

12. STOCK OPTIONS

In 2007, the Company adopted the 2007 Employee, Director and Consultant Stock Plan (the “2007 Plan”). Pursuant to the 2007 Plan, the Company’s Board of Directors (or committees and/or executive officers delegated by the Board of Directors) may grant incentive and nonqualified stock options to the Company’s employees, officers, directors, consultants and advisors. As of December 31, 2012, there were options to purchase an aggregate of 3,630,756 shares of Common Stock outstanding under the 2007 Plan and no shares available for future grants under the 2007 Plan.

On October 26, 2010, the Company’s Board of Directors adopted and the Company’s shareholders subsequently approved the 2010 Equity Incentive Plan, (the “2010 Plan”). The Company’s shareholders approved amendments to the 2010 Plan on August 3, 2011 and May 30, 2012 to increase the number of shares available for issuance under the 2010 Plan. The 2010 Plan provides for grants of incentive stock options to employees and nonqualified stock options and restricted Common Stock to employees, consultants and non-employee directors of the Company. As of December 31, 2012, the number of shares authorized for issuance under the 2010 Plan, as amended was 6,500,000 shares. As December 31, 2012, there were options to purchase an aggregate of 5,017,512 shares of Common Stock outstanding under the 2010 Plan and 1,475,717 shares available for future grants under the 2010 Plan. Options issued under the 2007 Plan and the 2010 Plan (collectively the “Plans”) are exercisable for up to 10 years from the date of issuance.

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)
Notes to Consolidated Financial Statements (Continued)

STOCK OPTIONS (continued)

Share-based compensation

For stock options issued and outstanding for the years ended December 31, 2012 and 2011, the Company recorded non-cash, stock-based compensation expense of $1,232,959 and $921,512, respectively, net of forfeitures.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model that uses the assumptions noted in the following table. Due to its limited operating history and limited number of sales of its Common Stock, the Company estimated its volatility in consideration of a number of factors including the volatility of comparable public companies. The Company uses historical data, as well as subsequent events occurring prior to the issuance of the financial statements, to estimate option exercises and employee terminations within the valuation model. The expected term of options granted under the Plans, all of which qualify as "plain vanilla," is based on the average of the contractual term (10 years) and the vesting period (generally 48 months). For non-employee options, the expected term is the contractual term. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option.

The assumptions used principally in determining the fair value of options granted were as follows:

	December 31, 2012	December 31, 2011
Risk-free interest rate	0.62-1.23%	0.97-3.05%
Expected dividend yield	0%	0%
Expected term (employee grants)	6.25	6.25
Expected volatility	75%	49%

A summary of option activity as of December 31, 2012 and changes for the year then ended are presented below:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2011	6,302,893	$ 0.76		
Granted	4,446,000	$ 2.03		
Forfeited	(1,345,605)	$ 2.03		
Exercised	(755,020)	$ 0.15		
Outstanding at December 31, 2012	8,648,268	$ 1.27	7.90	$5,616,414
Vested at December 31, 2012	3,882,733	$ 0.68	6.27	$4,407,390

The weighted average grant-date fair value of options granted during years ended December 31, 2012 and 2011 was $1.28 and $1.14 per share, respectively. The total fair value of options that vested in years ended December 31, 2012 and 2011, was $1,186,098 and $1,324,325, respectively. As of December 31, 2012, there was approximately $3,987,404 of total unrecognized compensation expense, related to non-vested share-based option compensation arrangements. The unrecognized compensation expense is estimated to be recognized over a period of 3.07 years at December 31, 2012.

In September 2011, the Company granted 80,000 shares of Common Stock under the 2010 Plan to a consultant as a restricted stock award with 30,000 shares vesting upon FDA clearance of an Investigational Device

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

STOCK OPTIONS (continued)

Exemption to permit the commencement of a human clinical trial and 50,000 shares vesting upon FDA approval of the Company's biopolymer scaffolding device to treat spinal cord injuries. The Company had previously determined that the vesting of the 30,000 shares was probable and the fair value of these shares at $23,400 was being amortized over an eight month period from September 2011 through April 2012. In March of 2012, the contract with the consultant was terminated and the consultant had no vested right to the restricted stock, so accordingly, the $11,700 of expense previously recorded was reversed in 2012.

13. WARRANTS

The following presents information about warrants to purchase Common Stock issued and outstanding at December 31, 2012:

Year Issued	Classification	Number of Warrants	Exercise Price	Date of Expiration
2010	Derivative	13,387,994	$ 1.40	10/26/2015-12/3/2015
2010	Derivative	1,940,157	$ 1.00	9/26/2015-12/3/2015
2011	Equity	16,071	$ 1.40	6/17/2018
2011	Equity	343,137	$ 3.06	12/21/2016
2012	Equity	36,145	$ 1.66	10/5/2019
Total		15,723,504		
Weighted average exercise price			$ 1.36	
Weighted average life in years				2.9

14. EMPLOYEE BENEFIT PLAN

In November 2006, the Company adopted a 401(k) plan (the "Plan") covering all employees. Employees must be 21 years of age in order to participate in the Plan. Under the Plan, the Company has the option to make matching contributions. For the years ended December 31, 2012 and 2011, the Company made matching contributions in the form of shares of common stock. For the year ended December 31, 2012 and 2011, the Company issued 47,105 and 39,848 shares of common stock, respectively, and related fair values of $91,524 and $41,662, respectively, were recorded as expense in the Statement of Operations.

15. INTELLECTUAL PROPERTY LICENSE

The Company has obtained a world-wide exclusive license (the "CMCC License") for patents co-owned by Massachusetts Institute of Technology and Harvard's Children's Hospital initially covering the use of biopolymers to treat spinal cord injuries, and to promote the survival and proliferation of human stem cells in the spinal cord. During 2011, the Company obtained additional rights for use in the field of peripheral nerve injuries. 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 the licensor. In connection with the CMCC License, the Company paid an initial $75,000 licensing fee and is required to pay certain annual maintenance fees, milestone payments and royalties. During 2011, the Company paid $75,000 to expand the license and at December 31, 2011, accrued $50,000 for a milestone payment. License fees are capitalized and all costs associated with maintenance of the CMCC License are expensed as incurred (see Note 4).

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

16. COMMITMENTS AND CONTINGENCIES

On November 29, 2011 and as amended on September 17, 2012, the Company entered into a commercial lease for 26,150 square feet of office, laboratory and manufacturing space in Cambridge, Massachusetts ("Cambridge Lease"). The term of this lease is six years and three months, with one five-year extension option. The terms of the lease requires a standby letter of credit, as amended, in the amount of $311,000 (see Note 1).

The Cambridge Lease contains rent holidays and rent escalation clauses. The Company recognizes rent expense on a straight-line basis over the lease term and record the difference between the amount charged to expense and the rent paid as a deferred rent liability. As of December 31, 2012, the amount of deferred rent liability is $310,076 and is included in Accrued expenses.

It is the Company's policy to assess whether improvements made to the space rented under operating leases should be accounted for as lessor or lessee assets. If the landlord/lessor makes the improvements and presents us with the finished space on a "turnkey" basis, we view the assets as being lessor assets. When the Company does the remodeling work and receives an allowance that may or may not cover all the costs, the Company makes a judgment as to the classification between lessor and lessee assets. The Company considers an asset to be a lessor asset if all of the following criteria are met:

- the lease specifically requires the lessee to make the improvement,
- the improvement is fairly generic,
- the improvement increases the fair value of the property to the lessor, and
- the useful life of the improvement is longer than our lease term.

If any of the above criteria are not met, the Company considers the assets to be lessee assets, which are recorded as leasehold improvements in the balance sheet and payments received from the lessor to fund any portion of the cost of lessee assets are accounted for as lease incentives. Assets considered to be lessor assets are not reflected in the Company's Consolidated Balance Sheets. To the extent that the Company paid for such lessor assets and was not reimbursed through construction allowances, such net payments are recorded as leasehold improvements, which are amortized to rent expense over the lease term. As of December 31, 2012, such leasehold improvements totaled $298,222.

Pursuant to the terms of the non-cancelable lease agreements in effect at December 31, 2012, the future minimum rent commitments are as follows:

Year Ended December 31,	
2013	1,168,659
2014	1,198,265
2015	1,237,533
2016	1,263,642
2017	1,294,859
2018	1,045,752
Total	$7,208,710

Total rent expense for the years ended December 31, 2012 and 2011, including month-to-month leases, was $758,000 and $357,000, respectively.

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

COMMITMENTS AND CONTINGENCIES (continued)

Other Commitments

In January 2012, the Company entered into a research contract with the Geisenger Health System under which the Company is obligated to pay Geisenger $150,000 for a pre-clinical study that will evaluate the Company's hydrogel for the treatment of peripheral nerve injuries. During the first quarter of 2012, the Company made an up-front payment of $60,000 for this study and expensed this cost to Research and Development. The Company did not make any other payments under this contract during fiscal year 2012.

17. SUBSEQUENT EVENTS

Subsequent to December 31, 2012, the Company received insurance proceeds of approximately $1,100,000 from a settlement of a business interruption claim that covered the disruption of the Company's operations at its Cambridge, MA facility caused by water damage that occurred in November 2012. The insurance settlement will be recorded as a reduction of Research and Development Expense in the Statement of Operations for the three months ending March 31, 2013.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Our Disclosure Controls

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that material information required to be disclosed in our periodic reports filed under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, including Frank M. Reynolds, our chief executive and chief financial officer, to allow timely decisions regarding required disclosure. As of the end of the period covered by this Annual Report on Form 10-K, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13(a)-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2012, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurances regarding the reliability of financial reporting and the preparation of our consolidated financial statements in accordance with U.S. generally accepted accounting principles, or GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate.

With the participation of Frank M. Reynolds, our chief executive and chief financial officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2012 based on the framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based upon our assessment and the COSO criteria, management concluded that our internal control over financial reporting was effective as of December 31, 2012.

Limitations on Effectiveness of Controls and Procedures

Our management, including Frank M. Reynolds, our chief executive and chief financial officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include, but are not limited to, the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Changes in Internal Controls over Financial Reporting

During the fiscal quarter ended December 31, 2012, there have been no changes in our internal control over financial reporting that have materially affected or are reasonably likely to materially affect our internal controls over financial reporting.

Independent Public Accounting Firm's Report on Internal Control over Financial Reporting

The independent registered public accounting firm that audited our consolidated financial statements included in this Annual Report on Form 10-K has issued its report on the effectiveness of our internal control over financial reporting. This report appears below.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of InVivo Therapeutics Holdings Corp.:

We have audited InVivo Therapeutics Holdings Corp.'s (the "Company") internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (a) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (b) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (c) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, InVivo Therapeutics Holdings Corp. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of InVivo Therapeutics Holdings Corp. as of December 31, 2012 and 2011, and the related consolidated statements of operations, changes stockholders' deficit and cash flows for the periods then ended, and our report dated March 11, 2013, expressed an unqualified opinion on those consolidated financial statements.

/s/ Wolf & Company, P.C.

Boston, Massachusetts
March 11, 2013

Item 9B. OTHER INFORMATION

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required under this item is incorporated herein by reference to the information regarding directors, executive officers and corporate governance included in our proxy statement for our 2013 Annual Meeting of Stockholders.

Item 11. EXECUTIVE COMPENSATION

The information required under this item is incorporated herein by reference to the information regarding executive compensation included in our proxy statement for our 2013 Annual Meeting of Stockholders.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required under this item is incorporated herein by reference to the information regarding security ownership of certain beneficial owners and management and related stockholder matters included in our proxy statement for our 2013 Annual Meeting of Stockholders.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required under this item is incorporated herein by reference to the information regarding certain relationships and related transactions and director independence included in our proxy statement for our 2013 Annual Meeting of Stockholders.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required under this item is incorporated herein by reference to the information regarding principal accounting fees and services included in our proxy statement for our 2013 Annual Meeting of Stockholders.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Financial Statements.

The financial statements listed in the Index to Consolidated Financial Statements appearing in Item 8 are filed as part of this report.

Financial Statement Schedules.

All financial statement schedules have been omitted as they are either not required, not applicable, or the information is otherwise included.

Exhibits.

The exhibits listed in the Exhibit Index immediately preceding the exhibits are filed as part of this report.

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INVIVO THERAPEUTICS HOLDINGS CORP.

Date: March 12, 2013

By: */s/ Frank M. Reynolds*
Name: Frank M. Reynolds
Title: Chief Executive Officer and Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	*Title*	*Date*
/s/ Frank M. Reynolds *Frank M. Reynolds*	*Chairman, Chief Executive Officer and Chief Financial Officer (Principal Executive, Financial and Accounting Officer)*	*March 12, 2013*
/s/ George Nolen *George Nolen*	*Director*	*March 12, 2013*
/s/ Kenneth DiPietro *Kenneth DiPietro*	*Director*	*March 12, 2013*
/s/ Richard J. Roberts *Richard J. Roberts*	*Director*	*March 12, 2013*
/s/ Adam K. Stern *Adam K. Stern*	*Director*	*March 12, 2013*

EXHIBIT INDEX

2.1	Agreement and Plan of Merger, dated October 4, 2010 , by and between Design Source, Inc. and InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 2.2 to the Company's Current Report on Form 8-K, as filed with the SEC on October 6, 2010).
2.2	Agreement and Plan of Merger and Reorganization, dated as of October 26, 2010 , by and among InVivo Therapeutics Holdings Corp. (f/k/a Design Source, Inc.), a Nevada corporation, InVivo Therapeutics Acquisition Corp., a Delaware corporation and InVivo Therapeutics Corporation, a Delaware corporation (incorporated by reference from Exhibit 2.1 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
2.3	Certificate of Merger (incorporated by reference from Exhibit 2.2 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
3.1	Articles of Incorporation of InVivo Therapeutics Holdings Corp., as amended (incorporated by reference from Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2010, as filed with the SEC on November 14, 2010).
3.2	Amended and Restated Bylaws of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on April 24, 2012).
4.1	Form of Bridge Warrant of InVivo Therapeutics Corporation (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
4.2	Form of Investor Warrant of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 4.3 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
4.3(i)	Form of Warrant of InVivo Therapeutics Holdings Corp. ($01.00 exercise price) issued to Placement Agent (incorporated by reference from Exhibit 4.2 to the Company's Current Report on Form 8-K, as filed with the SEC on December 9, 2010 .)
4.3(ii)	Form of Warrant of InVivo Therapeutics Holdings Corp. ($01.40 exercise price) issued to Placement Agent (incorporated by reference from Exhibit 4.3 to the Company's Current Report on Form 8-K, as filed with the SEC on December 9, 2010 .)
4.4	Form of Warrant of InVivo Therapeutics Holdings Corp. issued to Bridge Lenders (incorporated by reference from Exhibit 4.5 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
4.5	Form of Lock-Up Agreement (incorporated by reference from Exhibit 10.7 to the Company's Current Report on Form 8-K, as filed with the SEC on December 9, 2010 .)
4.6	Warrant dated June 17, 2011 issued to Square 1 Bank (incorporated by reference from Exhibit 4.7 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011, as filed with the SEC on March 15, 2012)
4.7	Specimen Common Stock Certificate (incorporated by reference from Exhibit 4.7 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011, as filed with the SEC on March 15, 2012).
4.8	Warrant dated October 5, 2012 issued to Massachusetts Development Finance Agency (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on March 15, 2012

10.1	Form of Securities Purchase Agreement between InVivo Therapeutics Corporation and the Bridge Lenders (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
10.2	Escrow Agreement, by and among InVivo Therapeutics Corp., InVivo Therapeutics Holdings Corp. and Signature Bank (incorporated by reference from Exhibit 10.2 to the Company's Registration Statement on Form S-1 (File No. 333-171998), as filed with the SEC on February 1, 2011).
10.3	Form of Subscription Agreement, by and between InVivo Therapeutics Holdings Corp. and the investors in the offering (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on December 9, 2010 .)
10.4	Form of Registration Rights Agreement, by and between InVivo Therapeutics Holdings Corp. and the investors in the offering (incorporated by reference from Exhibit 10.4 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
10.5	Split-Off Agreement, by and among InVivo Therapeutics Holdings Corp., DSource Split Corp., Peter Reichard, Lawrence Reichard and Peter Coker (incorporated by reference from Exhibit 10.5 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
10.6	General Release Agreement, dated as of October 26, 2010 , by and among InVivo Therapeutics Corp., DSource Split Corp., Peter Reichard, Lawrence Reichard and Peter Coker (incorporated by reference from Exhibit 10.6 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
10.7(i)*	Amended and Restated Executive Employment Agreement by and between InVivo Therapeutics Holdings Corp. and Frank Reynolds, dated March 15, 2011 (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on March 17, 2011).
10.7(ii)*	Amended and Restated Executive Employment Agreement by and between InVivo Therapeutics Holdings Corp. and Frank Reynolds, dated March 5, 2012 (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on March 8, 2012).
10.8*	Employment Agreement between Christopher Pritchard and InVivo Therapeutics Corp. (incorporated by reference from Exhibit 10.8 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
10.9*	InVivo Therapeutics Corp. 2007 Stock Incentive Plan (incorporated by reference from Exhibit 10.9 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
10.10*	InVivo Therapeutics Holdings Corp. 2010 Equity Incentive Plan (incorporated by reference from Exhibit 10.10 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
10.11*	Amendment No. 1 to the InVivo Therapeutics Holdings Corp. 2010 Equity Incentive Plan (incorporated by reference from Appendix IV to the Company's Definitive Proxy Statement, as filed with the SEC on July 19, 2011).
10.12(i)*	Form of Incentive Stock Option Agreement by and between InVivo Therapeutics Corp. and participants under the 2007 Stock Incentive Plan (incorporated by reference from Exhibit 10.11(i) to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
10.12(ii)*	Form of Non-Qualified Stock Option Agreement by and between InVivo Therapeutics Corp. and participants under the 2007 Stock Incentive Plan (incorporated by reference from Exhibit 10.11(ii) to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).

10.13(i)*	Form of Incentive Stock Option Agreement by and between InVivo Therapeutics Holdings Corp. and participants under the 2010 Equity Incentive Plan (incorporated by reference from Exhibit 10.12(i) to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 , as filed with the SEC on March 24, 2011).
10.13(ii)*	Form of Non-Qualified Stock Option Agreement by and between InVivo Therapeutics Holdings Corp. and participants under the 2010 Equity Incentive Plan (incorporated by reference from Exhibit 10.12(ii) to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 , as filed with the SEC on March 24, 2011).
10.14	Form of Scientific Advisory Board Agreement entered into by InVivo Therapeutics Corp. (incorporated by reference from Exhibit 10.13 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
10.15	License Agreement dated July 2007 between InVivo Therapeutics Corporation and Children's Medical Center Corporation (incorporated by reference from Exhibit 10.1 to Amendment No. 2 to the Company's Quarterly Report on Form 10-Q/A for the quarter ended March 31, 2011, as filed with the SEC on July 18, 2011).
10.16	Amendment One to the License Agreement, dated May 12, 2011, by and between Children's Medical Center Corporation and InVivo Therapeutics Corporation (incorporated by reference from Exhibit 10.22 to the Amendment No. 4 to the Company's Registration Statement on Form S-1/A (File No. 333-171998), as filed with the SEC on July 19, 2011).
10.17	Finder's Fee Agreement dated August 18, 2010 , between InVivo Therapeutics Corporation and Placement Agent (incorporated by reference from Exhibit 10.3 to the Company's Current Report on Form 8-K, as filed with the SEC on December 9, 2010 .)
10.18	Placement Agent Agreement dated October 4, 2010 , between InVivo Therapeutics Corp. and Placement Agent (incorporated by reference from Exhibit 10.4 to the Company's Current Report on Form 8-K, as filed with the SEC on December 9, 2010 .)
10.19	Finder's Fee Agreement dated October 26, 2010 , between InVivo Therapeutics Corp. and Placement Agent (incorporated by reference from Exhibit 10.5 to the Company's Current Report on Form 8-K, as filed with the SEC on December 9, 2010 .)
10.20	Master Services Agreement dated October 26, 2010 , between InVivo Therapeutics Corp. and Placement Agent (incorporated by reference from Exhibit 10.6 to the Company's Current Report on Form 8-K, as filed with the SEC on December 9, 2010 .)
10.21	Founders' Agreement among InVivo Therapeutics Corporation, Francis M. Reynolds, Robert Langer and Yang Teng dated November 1, 2006 (incorporated by reference from Exhibit 10.18 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
10.22	Form of Indemnification Agreement, as executed by Frank M. Reynolds, George Nolen, Christi M. Pedra, Richard J. Roberts and Adam K. Stern (incorporated by reference from Exhibit 10.19 to the Company's Registration Statement on Form S-1 (File No. 333-171998), as filed with the SEC on February 1, 2011).
10.23*	InVivo Therapeutics Holdings Corp. Director Compensation Plan, adopted December 10, 2010 (incorporated by reference from Exhibit 10.20 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 , as filed with the SEC on March 24, 2011).
10.24*	Employment Offer Letter from the Company to Dr. Edward D. Wirth III, dated September 24, 2011 (incorporated by reference from Exhibit 99.1 to the Company's Current Report on Form 8-K, as filed with the SEC on October 14, 2011).

10.25	Lease Agreement, dated November 29, 2011, between InVivo Therapeutics Corporation and RB Kendall Fee, LLC (incorporated by reference from Exhibit 10.25 to the Company's Registration Statement on Form S-1 (File No. 333-178584), as filed with the SEC on December 16, 2011).
10.26	Lease Guaranty, dated November 30, 2011, by InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 10.26 to the Company's Registration Statement on Form S-1 (File No. 333-178584), as filed with the SEC on December 16, 2011).
10.27	Securities Purchase Agreement, dated December 21, 2011, by and between the Company and Ingenieria E Inversiones Ltda. (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on December 22, 2011).
10.28	Common Stock Purchase Warrant dated December 21, 2011 and issued by the Company to Ingenieria E Inversiones Ltda. (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on December 22, 2011).
10.29*	InVivo Therapeutics Holdings Corp. Annual Cash Bonus Plan for Executive Officers (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on March 8, 2012).
10.30*	InVivo Therapeutics Holdings Corp. 2010 Equity Incentive Plan, as amended (incorporated by reference to Appendix A to the Company's Schedule 14A Proxy Statement, as filed with the SEC on April 19, 2012).
10.31	Amendment to Lease Agreement between InVivo Therapeutics Corporation and RB Kendall Fee, LLC, dated September 17, 2012.
10.32	Promissory Note dated October 5, 2012 in favor of Massachusetts Development Finance Agency (incorporated by reference from Exhibit 10.1 to the Company's Current Report on From 8-K, as filed with the SEC on October 9, 2012).
21	Subsidiaries of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 21.1 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
23.1	Consent of Wolf & Company, P.C.
31.1	Certification by the Principal Executive Officer and Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Label Linkbase Document
101.PRE**	XBRL Taxonomy Presentation Linkbase Document

* Management contract or compensatory plan or arrangement filed in response to Item 15(a)(3) of Form 10-K.

** Pursuant to Rule 406T of Regulation S-T, the interactive files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

Exhibit 10.31

FIRST AMENDMENT OF LEASE

THIS FIRST AMENDMENT OF LEASE (the " First Amendment ") is made this 17th day of September, 2012 by and between **RB KENDALL FEE, LLC** , a Delaware limited liability company (" Landlord ") and **IN VIVO THERAPEUTICS CORPORATION** , a Delaware corporation (" Tenant ").

BACKGROUND :

A. Reference is made to a certain Lease Agreement dated November 29, 2011 by and between Landlord and Tenant, demising approximately 20,917 rentable square feet of space on the fourth (4th) floor of Building 1400 (the " Existing Premises ") in One Kendall Square, Cambridge, Massachusetts (the " Complex "). Capitalized terms used but not defined herein shall have the same meaning as in the Lease.

B. Landlord and Tenant are the current holders, respectively, of the lessor's and lessee's interests in the Lease.

C. Landlord and Tenant desire to expand the Existing Premises to include additional space within Building 1400 in the Complex and to further amend the Lease, all as set forth herein.

AGREEMENTS :

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree and amend the Lease as follows:

1. Expansion Space and Additional Space .

(a) Effective upon the later of the date that (i) this Amendment has been executed and delivered by Landlord and Tenant and approved in writing by Landlord's mortgagee, and (ii) Landlord delivers exclusive possession of the Expansion Space (hereinafter defined) to Tenant in the Delivery Condition (the " Expansion Commencement Date "), approximately 5,233 rentable square feet of space on the fourth (4th) floor of Building 1400 identified on the plan attached hereto as Exhibit 1 as the Expansion Space (the " Expansion Space ") shall be deemed added to and incorporated into the Existing Premises, whereupon the Total Rentable Area of the Premises shall be increased to 26,150 square feet. The demise and use of the Expansion Space shall be upon and subject to all of the terms and conditions of the Lease, except as expressly set forth in this First Amendment. Tenant acknowledges and agrees that the Expansion Space may be used for general office purposes only and not for any laboratory or chemical storage uses. All references to the Premises in the Lease shall include the Expansion Space and all references to Exhibit 2 in the Lease shall be deemed to include and refer to Exhibit 1 attached hereto, as applicable. The Expansion Space shall be delivered in broom clean condition, free of all occupants, personal property, trade fixtures and equipment (with the exception of the Remaining Furniture, Fixtures and Equipment hereinafter defined), and with all Building systems serving the Expansion Space in good working condition, with new flooring and ceiling tiles (using Building standard materials) installed in the common area corridor leading to the Expansion Space and new paint on the radiator in said corridor (using Building standard colors) (collectively, the " Delivery Condition "), and, shall otherwise be accepted by Tenant in "as-is", "where-is" condition without any warranty of fitness for use or occupancy, expressed or implied, except as otherwise expressly set forth herein or in the Lease. Tenant agrees that

Landlord has no work to perform in or on the Expansion Space to prepare same for Tenant's use and occupancy except as set forth in this First Amendment. The foregoing shall in no way derogate from Landlord's ongoing repair and maintenance obligation as may be set forth in the Lease.

(b) Effective upon the Expansion Commencement Date, the former common hallways and bathroom shown on the plan attached hereto as Exhibit 1A (the " Additional Space ") shall be considered be deemed added to and incorporated into the Existing Premises. All references to the Premises in the Lease shall include the Additional Space and all references to Exhibit 2 in the Lease shall be deemed to include and refer to Exhibit 1A attached hereto, as applicable. Landlord shall cause the Additional Space to be cleaned on Monday through Friday (excepting Massachusetts or City of Cambridge legal holidays) in a manner consistent with cleaning standards generally prevailing in comparable buildings.

(c) The " Expansion Space Rent Commencement Date " shall be the later to occur of November 1, 2012 and the Expansion Space Commencement Date. Prior to the Expansion Space Rent Commencement Date Tenant shall continue to pay Yearly Rent, and or other amounts payable under the Lease, for the Existing Premises in the amounts provided for in the Lease as of the date hereof and as amended herein.

2. Term . The term of the Lease with respect to the Existing Premises commenced on July 12, 2012. The term of the Lease with respect to the Expansion Space and the Additional Space shall commence on the Expansion Commencement Date and thereafter shall be co-terminous with the term of the Lease, expiring on October 31, 2018, unless the Lease is otherwise terminated or extended pursuant to the terms and conditions of the Lease.

3. Yearly Rent . Commencing on the Expansion Space Rent Commencement Date, the Yearly Rent due under the Lease with respect to the Expansion Space shall be as follows:

Period	Yearly Rent	Monthly Rent	Rent Per Rentable Square Foot
Expansion Space Rent Commencement Date – October 31, 2013	$198,854.00	$16,571.17	$ 38.00
November 1, 2013 – October 31, 2014	$204,087.00	$17,007.25	$ 39.00
November 1, 2014 – October 31, 2015	$225,908.61	$18,825.72	$ 43.17
November 1, 2015 – October 31, 2016	$231,141.61	$19,261.80	$ 44.17
November 1, 2016 – October 31, 2017	$236,374.61	$19,697.88	$ 45.17
November 1, 2017 – October 31, 2018	$241,607.61	$20,133.97	$ 46.17

The Yearly Rent for the entire Premises, including the Expansion Space, shall be payable in accordance with the terms of the Lease and shall be in addition to all other amounts due and payable by Tenant pursuant to the Lease.

4. Escalation . (a) In addition to payment of the Tax Share in connection with the Existing Premises, Tenant shall pay to Landlord with regard to the Expansion Space, with respect to any fiscal period in respect of which Taxes are due and payable during the term of the Lease (the " Tax Period "), the sum of: (x) 4.05% (the " Tenant's Expansion Proportionate Building Share ") of the amount (if any) by which Building Taxes for such Tax Period exceeds the Building Taxes in Fiscal Year 2014 (the " Real Estate Tax Base Year ") (the " Building Tax Base "), plus (y) 0.82% (the " Tenant's Expansion Proportionate Common Share ") of the amount (if any) by which Common Area Taxes for such Tax Period exceeds the Common Area Taxes in the Real Estate Tax Base Year (the " Common Area Tax Base "), such sum being hereinafter referred to as " Tax Excess" . Tenant's obligation to pay the Tax Excess hereunder shall commence on July 1, 2014. Taxes in respect of the Expansion Space shall be calculated in the manner set forth in the Lease. In implementation and not in limitation of the foregoing, Tenant shall remit to Landlord pro rata monthly installments on account of projected Tax Excess, calculated by Landlord on the basis of the most recent Tax data or budget available. If the total of such monthly remittances on account of any Tax Period is greater than the actual Tax Excess for such Tax Period, Landlord shall credit the difference against the next installment of rent or other charges due to Landlord under the Lease, or if the term has expired, Landlord shall promptly repay such excess to Tenant. If the total of such remittances is less than the actual Tax Excess for such Tax Period, Tenant shall pay the difference to Landlord within thirty (30) days of when billed therefor **.** Appropriate credit against Tax Excess shall be given for any refund obtained by reason of a reduction in any Taxes by the Assessors or the administrative, judicial or other governmental agency responsible therefor. The original computations, as well as reimbursement or payments of additional charges, if any, or allowances, if any, under the provisions of this paragraph shall be based on the original assessed valuations with adjustments to be made at a later date when the tax refund, if any, shall be paid to Landlord by the taxing authorities. Expenditures for reasonable legal fees and for other similar or dissimilar expenses incurred in obtaining the tax refund may be charged against the tax refund before the adjustments are made for the Tax Period.

(b) In addition to payment of the Operating Expense Share in connection with the Existing Premises, Tenant shall pay to Landlord with regard to the Expansion Space, with respect to any Operating Year, the sum of: (x) 4.05% (the " Tenant's Expansion Proportionate Building Share ") of the amount (if any) by which Building Operating Costs for such Operating Year exceeds Building Operating Costs in the calendar year 2013 (the " Operating Costs Base Year "), plus (y) 0.82% (the " Tenant's Expansion Proportionate Common Share" of the amount (if any) by which Common Area Operating Costs for such Operating Year exceeds Common Area Operating Costs in the Operating Costs Base Year, such sum being hereinafter referred to as " Operating Expense Excess ". Tenant's obligation to pay the Operating Expense hereunder shall commence on January 1, 2014. Operating Costs in respect of the Expansion Space shall be calculated in the manner set forth in the Lease, and the "gross-up" provision in Section 9.2(f)(6) of the Lease shall apply, without limitation, to the Operating Cost Base Year. In implementation and not in limitation of the foregoing, Tenant shall remit to Landlord pro rata monthly installments on account of projected Operating Expense Excess, calculated by Landlord on the basis of the most recent Operating Costs date or budget available. If the total of such monthly remittances on account of any Operating Year is greater than the actual Operating Expense Excess for such Operating Year, Tenant may credit the different against the next installment of rent or other charges due to Landlord hereunder. If the total of such remittances is less than actual Operating Expense Excess for such Operating Year, Tenant shall pay the difference to Landlord within thirty (30) days after being billed therefor.

5. Utilities. In addition to the Yearly Rent, and other amounts payable under the Lease, Tenant shall be obligated to pay, when billed by Landlord, for its electricity usage in the Premises, including the Expansion Space, in accordance with the provisions of Section 8.1 of the Lease.

6. Tenant's Improvements; Expansion Improvement Allowance. After the date of this First Amendment, Tenant may begin its Tenant's leasehold improvements to the Expansion Space (" Tenant's Improvements ") in the same manner and in accordance with the terms and conditions of the Lease. Prior to commencing work on Tenant's Improvements, Tenant's contractors and subcontractors shall provide Landlord with evidence of builder's risk, general liability, automobile liability, workers compensation, and excess/umbrella insurance policies in coverages reasonably acceptable to Landlord, such policies to be maintained throughout the construction of Tenant's Improvements. In connection with Tenant's Improvements, Landlord shall reimburse Tenant up to a maximum of Twenty-five and 00/100 Dollars ($25.00) per rentable square foot of the Expansion Space, not to exceed One Hundred Thirty Thousand Eight Hundred Twenty Five and 00/100 Dollars ($130,825.00) (" Expansion Improvement Allowance ") in the aggregate toward the actual cost (which cost shall include, without limitation, the costs of construction, the cost of permits and permit expediting, and all architectural and engineering services obtained by Tenant in connection therewith) of Tenant's Improvements relating to the Expansion Space that are completed solely during the first six (6) months after the date of this First Amendment. The Expansion Improvement Allowance shall be utilized for so-called "hard" costs and building improvements to the Expansion Space pursuant to Tenant's Plans, and for so-called "soft" costs limited to architectural and design costs, permit fees, construction management fees, reasonable moving costs, and legal fees relating to Tenant's fit-up of and/or move into the Expansion Space. So long as Tenant is not in default of the Lease beyond any Grace Period, payment of the Expansion Improvement Allowance shall be paid by Landlord to Tenant in one (1) lump sum payment based upon a request for payment submitted by Tenant upon the completion of Tenant's Improvements. Such request for payment shall be accompanied by a written certification reasonably satisfactory to Landlord by Tenant's architect that all work has been completed, along with any other support documentation reasonably required by Landlord in connection therewith, including lien waivers, provided, however, that the Expansion Improvement Allowance (or a suitable portion thereof) may not be released by Landlord if any liens, notices of contract or similar instruments relating to Tenant's Improvements exist or appear in the record title to the Building or Complex. Any and all costs for the construction of the Expansion Space above the Expansion Improvement Allowance shall be paid by Tenant to the applicable contractors, subcontractors, and material suppliers. In the event of a default under the Lease (or an event which with passage of time or the giving of notice, or both, would constitute a default) or if a lien has been filed by one of Tenant's contractors, subcontractors or material suppliers (or in Landlord's good faith belief the filing of such a lien is likely), Landlord reserves the right to make any payment (or portion thereof) of the Expansion Improvement Allowance payable jointly to Tenant and its general contractor (or subcontractor or supplier) or directly to such contractor, subcontractor or supplier. Tenant's Improvements shall be in conformity with plans and specifications ("Tenant's Plans") submitted to and approved by Landlord (such approval not to be unreasonably withheld, delayed or conditioned), and constructed by a contractor approved by Landlord (such approval not to be unreasonably withheld, delayed or conditioned) in the same manner and in accordance with the terms of the Lease.

7. Furniture; Bill of Sale. Landlord and Tenant acknowledge that certain furniture, fixtures and equipment presently located in the Expansion Space shall remain in the Expansion Space upon delivery of the Expansion Space to Tenant. Landlord hereby agrees to execute and deliver to Tenant a Bill of Sale in the form attached hereto as Exhibit A (the " Bill of Sale ") conveying to Tenant all of Landlord's right, title and interest in and to the furniture, fixtures and equipment in the Premises as of the date hereof more particularly described on Schedule 1 to the Bill of Sale (collectively, the " Remaining Furniture, Fixtures and Equipment ").

8. Extension Payment . As further consideration for this First Amendment, upon the Expansion Commencement Date, Landlord shall pay to Tenant an amount equal to the Termination Payment made by the prior tenant of the Expansion Space, which Landlord represents to be $43,259.47.

9. Additional Security Deposit . Upon the execution of this First Amendment by Tenant, Tenant shall deliver to Landlord an amendment to the existing Letter of Credit (in the current amount of $294,662.00) being held by the Landlord under the Lease increasing the amount under the Letter of Credit by $16,571.17 for a total Letter of Credit amount of $311,233.17 or deliver a Substitute Letter of Credit (as defined in Section 29.13 of the Lease) in an amount equal to $311,233.17 representing the combined security amount required under the Lease and this First Amendment. The foregoing shall not derogate from Tenant's ongoing right to reduce the amount of the Letter of Credit under Section 29.13 of the Lease, and any future 25% reductions shall be applied to the amount of the Letter of Credit as increased hereby.

10. Parking . Effective upon the date of this First Amendment, Tenant shall be entitled to a total of six (6) additional monthly parking passes (for a total of twenty seven (27)) available to Tenant for use in the One Kendall Square Garage pursuant to, and in accordance with, Section 29.14 of the Lease, except that, as of the date of this First Amendment, Landlord represents that the current prevailing rate for such passes is $225.00 per month, which rate may vary from time to time.

11. Amendment re Subleasing and Assignments . The last sentence of Section 16.1 is amended to read as follows: "Tenant shall not collaterally assign this Lease (or any portion thereof) or permit any assignment of this Lease by mortgage, other encumbrance or operation of law, without, in each instance, having first received the express, written consent of Landlord and provided Landlord has approved the form of such assignment, which consent and approval shall not be unreasonably withheld, conditioned or delayed."

12. Brokers . Landlord and Tenant each warrant and represent to the other that they have dealt with no brokers in connection with the negotiation or consummation of this First Amendment other than Beal and Company, Inc. and CBRE NE (collectively, the " Brokers ") and in the event of any brokerage claim against either party by any person claiming to have dealt with either Landlord or Tenant in connection with this First Amendment, other than the Brokers, the party with whom such person claims to have dealt shall defend and indemnify the other party against such claim. Landlord shall pay any commission due the Brokers pursuant to a separate agreement.

13. Consent and Reaffirmation of Guarantor . The undersigned Guarantor acknowledges and consents to this First Amendment and confirms that its Guaranty dated November 30, 2011, remains in full force and effect and continues to guaranty the Lease as amended herein.

14. Reaffirmation . In all other respects the Lease shall remain unmodified and shall continue in full force and effect, as amended hereby. The parties hereby ratify, confirm, and reaffirm all of the terms and conditions of the Lease, as amended hereby.

15. Counterparts . This First Amendment may be signed in any number of counterparts, each of which so executed shall be deemed original and such counterparts shall together constitute the First Amendment. Facsimile signatures shall be sufficient and binding.

IN WITNESS WHEREOF the parties hereto have executed this First Amendment of Lease on the date first written above in multiple copies, each to be considered an original hereof, as a sealed instrument.

LANDLORD:

RB KENDALL FEE, LLC

By: /s/ Robert L. Beal
Robert L. Beal, its authorized signatory

TENANT:

IN VIVO THERAPEUTICS CORPORATION

By: /s/ Frank Reynolds
Frank Reynolds
Chief Executive Officer

GUARANTOR:

IN VIVO THERAPEUTICS HOLDING CORPORATION

By: /s/ Frank Reynolds
Frank Reynolds
Chief Executive Officer

EXHIBIT 1
PLAN FOR EXPANSION SPACE

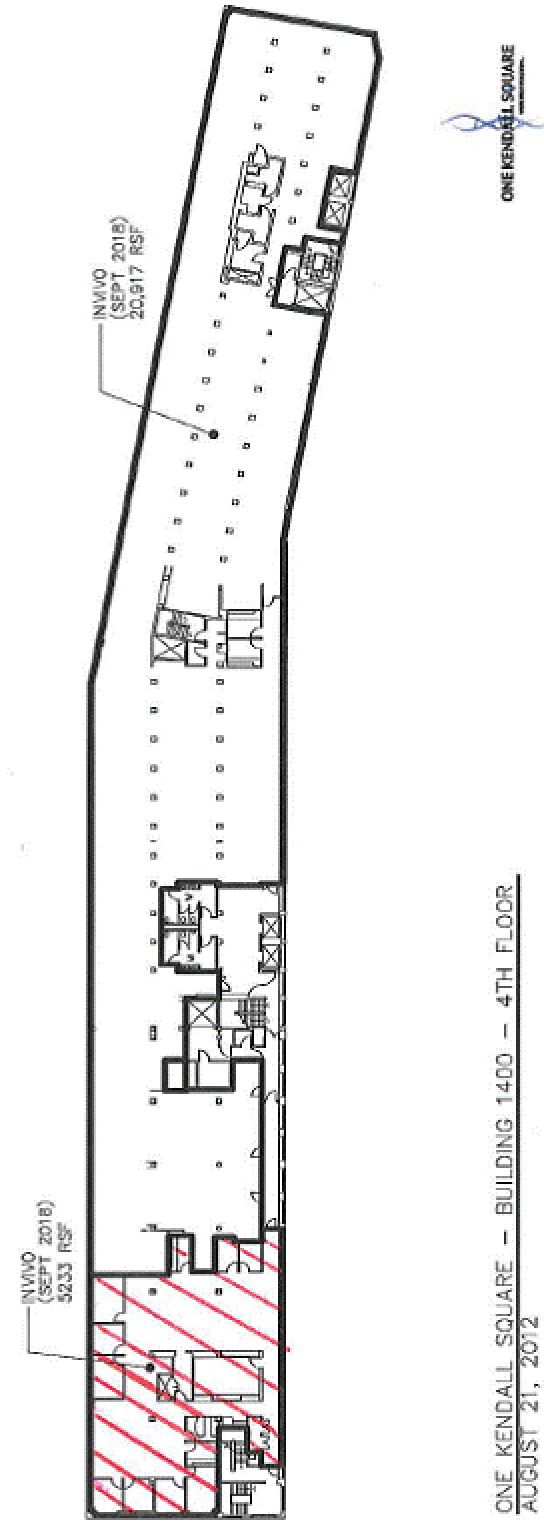

EXHIBIT 1A
PLAN FOR ADDITIONAL SPACE

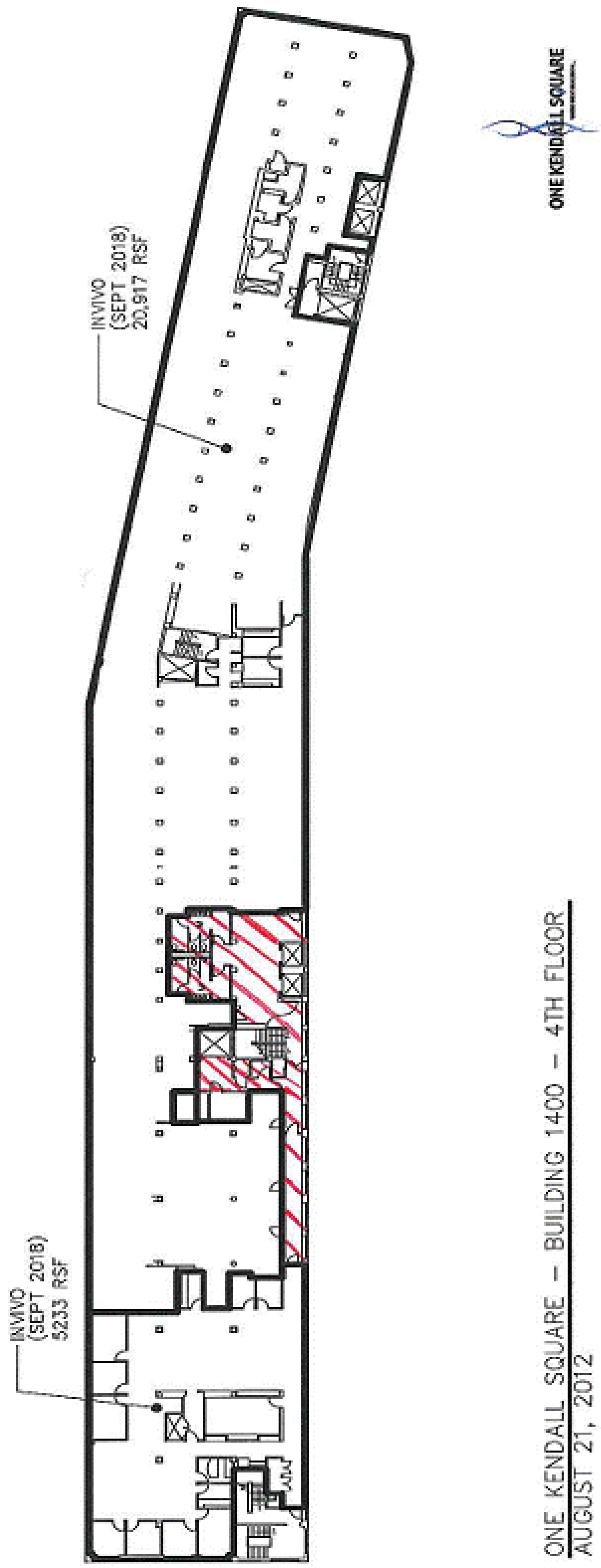

EXHIBIT A

BILL OF SALE

By this instrument dated as of September 17, 2012, for good and valuable consideration, the receipt of which is hereby acknowledged, **RB KENDALL FEE, LLC** , a Delaware limited liability company, having a mailing address c/o The Beal Companies, LLP, 177 Milk Street, Boston, Massachusetts ("Transferor") does hereby grant, bargain, transfer, assign, sell and convey unto **IN VIVO THERAPEUTICS CORPORATION** , a Delaware corporation, having a mailing address of One Kendall Square, Building 1400, 4 th Floor, Cambridge, Massachusetts (the "Transferee") all of the furniture, fixtures and equipment (the "Remaining Furniture, Fixtures and Equipment") more particularly described on Schedule 1 attached hereto and located in, on or at the premises located on the fourth (4 th) floor of Building 1400 at One Kendall Square, Cambridge, Massachusetts, as described in the First Amendment of Lease of even date herewith (the "First Amendment").

Transferor hereby warrants that it is the lawful owner of the Remaining Furniture, Fixtures and Equipment described above and has good right to sell the same to Transferee.

Subject to the foregoing, Transferee acknowledges and agrees that the Remaining Furniture, Fixtures and Equipment is hereby transferred to Transferee in its "as is" condition with all faults and with no representations or warranties of any kind except as specifically set forth herein, any warranty of merchantability or fitness is hereby expressly excluded. This instrument and all of its terms shall inure to the benefit of and be binding upon the undersigned and its successors and assigns.

EXECUTED as a sealed instrument as of the date written above.

TRANSFEROR:
RB KENDALL FEE, LLC , a Delaware limited liability company

By:______________________________
Robert L. Beal, its Authorized Signatory

TRANSFEREE:
IN VIVO THERAPEUTICS CORPORATION , a Delaware corporation

By:______________________________
Frank Reynolds
Chief Executive Officer

Schedule 1

9 office work stations

16 cubicle office work stations

2 conference tables

Approximately 20 miscellaneous office/visitor chairs

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statements (Nos. 333-183491, 333-173208, 333-176110 and 333-176111) on Form S-8 and Registration Statements (Nos. 333-178584 and 333-171998) on Form S-3 of our report dated March 11, 2013, relating to our audits of the consolidated financial statements of InVivo Therapeutics Holdings Corp. appearing in the Annual Report on Form 10-K of InVivo Therapeutics Holdings Corp. for the year ended December 31, 2012.

/s/ Wolf & Company, P.C.
Wolf & Company, P.C.
Boston, Massachusetts
March 11, 2013

Exhibit 31.1

SARBANES-OXLEY SECTION 302(a) CERTIFICATION

I, Frank M. Reynolds, certify that:

1. I have reviewed this Annual Report on Form 10-K of InVivo Therapeutics Holdings Corp.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 12, 2013

/s/ Frank M. Reynolds

Frank M. Reynolds, Principal Executive Officer and Principal Financial Officer

Exhibit 32.1

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of InVivo Therapeutics Holdings Corp. (the “Company”) on Form 10-K for the period ended December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Frank M. Reynolds, Chief Executive Officer and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: March 12, 2013

/s/ Frank M. Reynolds
Frank M. Reynolds, Chief Executive Officer and Chief Financial Officer