INVIVO THERAPEUTICS HOLDINGS CORP.
Form 10-K
March 15, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED DECEMBER 31, 2011**

¨ **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	**36-4528166**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
One Broadway, 14th Floor	**02142**

Cambridge, Massachusetts
(Address of principal executive offices) **(Zip Code)**

Registrant s telephone number, including area code: (617) 475-1520

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 x

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 x

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 x 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 x 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. x

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 x

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

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 30, 2011 was $ 24,020,023

As of March 12, 2012, the number of shares outstanding of the registrant s common stock, $0.00001 par value per share, was 63,781,404.

DOCUMENTS INCORPORATED BY REFERENCE

Designated portions of the Registrant s Proxy Statement for its 2012 Annual Meeting of Stockholders to be filed within 120 days after the Registrant s fiscal year end of December 31, 2011 are incorporated by reference into Part III of this Annual Report.

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INVIVO THERAPEUTICS HOLDINGS CORP.

ANNUAL REPORT ON FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2011

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PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K contains forward-looking statements within the meaning of the federal securities laws. These statements relate to anticipated future events, future results of operations or future financial performance. These forward-looking statements include, but are not limited to, statements relating to our ability to raise sufficient capital to finance our planned operations, market acceptance of our technology and product offerings, our ability to attract and retain key personnel, our ability to protect our intellectual property, and estimates of our cash expenditures for the next 12 to 36 months. 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.

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. The Risk Factors section of this annual report sets forth detailed risks, uncertainties and cautionary statements regarding our business and these forward-looking statements.

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.

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, 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.

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We intend to create new treatments for spinal cord injury. 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. A biocompatible hydrogel for local controlled release of methylprednisolone to treat acute spinal cord injuries and peripheral nerve injuries.

3. A biocompatible polymer scaffolding device seeded with autologous human neural stem cells to treat acute and chronic 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 first 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 will require FDA approval of a Pre-Market Approval Application (PMA) before the Company can start selling the product in the U.S.

We will be required to demonstrate safety and efficacy in human clinical studies before it can submit a PMA, to the FDA. 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 scaffolding device to the FDA on July 7, 2011. The FDA has provided comments to our IDE filing and we are in the process of responding to the FDA comments. We anticipate that our IDE will be approved by the FDA during 2012, but can give no assurance that the IDE will be approved. We plan to first conduct a pilot study in ten acute spinal cord patients followed by a larger pivotal study. The FDA must review and approve the PMA before we can start selling the product in the U.S. The completion of the human clinical studies and the FDA approval of the PMA could take between three to five years to achieve, depending on a number of factors including the FDA review and clearance process for the IDE, the clinical trial designs and amount of time it will take to enroll and treat patients, and the FDA review and approval process for the PMA. The FDA regulatory approval process is lengthy, and the outcome is 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.

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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.

Additional applications of our platform technologies include the potential treatment for, spinal cord injury following tumor removal, peripheral nerve damage, and postsurgical treatment of any transected nerve. Our first product, the biocompatible scaffolding device for the treatment of acute spinal cord injury, is regulated as a Class III medical device by the FDA. The product has been evaluated in animal studies and the Company submitted an IDE with the FDA on July 7, 2011, that if approved by the FDA will permit the commencement of human clinical studies. The FDA has provided the Company with comments to its IDE filing and the Company is in the process of responding to the FDA comments. The Company anticipates that its IDE will be approved by the FDA during 2012. The biocompatible hydrogel for the local release of methylprednisolone to treat acute spinal cord injuries and the biocompatible polymer scaffolding device seeded with autologous human neural stem cells to treat acute and chronic spinal cord injuries 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 are a development stage company, and as such face significant uncertainty regarding our future capital needs and timelines for our intended products.

Market Opportunity

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 $321,720 to $985,774, depending on the severity.
- The net present value (NPV) to maintain a quadriplegic injured at age 25 for life is $3,373,912.
- The NPV to maintain a paraplegic injured at age 25 for life is $2,138,824

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 2010.*

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.

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

	AVERAGE YEARLY EXPENSES (in 2010 dollars)		ESTIMATED LIFETIME COSTS BY AGE AT INJURY (NPV, Discounted at 2%)	
SEVERITY OF INJURY	**First Year**	**Each Subsequent Year**	**25 Years Old**	**50 Years Old**
High Tetraplegia (C1-C4)	$ 985,774	$ 171,183	$ 4,373,912	$ 2,403,828
Low Tetraplegia (C5-C8)	$ 712,308	$ 105,013	$ 3,195,853	$ 1,965,735
Paraplegia	$ 480,431	$ 63,643	$ 2,138,824	$ 1,403,646
Incomplete Motor Functional at Any Level	$ 321,720	$ 39,077	$ 1,461,255	$ 1,031,394

Source: National Spinal Cord Injury Statistical Center; February 2011 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 First 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 first 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

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(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.

Our Second Planned Product to be Developed: Local Controlled Release Drug Delivery

The second product we intend to develop is an injectable hydrogel designed to counteract the inflammatory environment that results 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 peaks during secondary injury. 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.

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Our Third Product to be Developed: Polymer Scaffold Seeded with Autologous Human Neural Stem Cells

The third product we intend to develop extends the biopolymer 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.

Our third 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.

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.

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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

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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).

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).

2nd 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

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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

3rd 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. Initial results are consistent with data from prior monkey and rodent studies.

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Commercialization Strategy

Clinical Regulatory Plan

Our PLGA biopolymer scaffolding product is expected to be regulated as a Class III medical device by the FDA. We will be required to demonstrate safety and efficacy in a human clinical trial before we can submit a PMA for FDA approval. 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 we are in the process of responding to the FDA comments. We anticipate that the IDE will be approved by the FDA during 2012, but can give no assurance that the IDE will be approved.

We first plan to conduct a pilot clinical study to evaluate the device in ten acute spinal cord injury patients. We are also planning a larger follow-on pivotal human study in acute spinal cord injury patients after the pilot study is completed. The clinical development timeline is subject to a number of risks that could delay the filing of a PMA or cause a PMA never to be filed. The FDA will review the PMA and there could be significant delays in the review process. There is also a risk that the FDA will never approve the PMA. These risks are described in the section entitled Risk Factors. Even if the FDA approves the 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.

Our regulatory team is led by David Feigal, MD, a consultant to the Company and a member of our Business Advisory Board. Dr. Feigal recently served as Vice-President, Regulatory at Amgen, Inc. and earlier was the number-two executive at the FDA from 1992 to 2006. During his tenure, he was head of the FDA s Center for Devices for five years and head of the Center for Biologics for five years. For our day-to-day handling of FDA processes, we will hire a Director of Regulatory & Clinical Affairs who will be responsible for managing our regulatory affairs.

Janice Hogan, a managing partner of the Philadelphia office of Hogan Lovells US LLP, serves as our FDA consultant. Ms. Hogan has over twenty-five years of experience in representing spine industry companies to the FDA such as Johnson & Johnson s DePuy Spine, Synthes Spine, Abbott Spine, Stryker Spine, and Medtronic Spine.

Manufacturing and Product Delivery Plan

We believe that the raw material polymers for our first device product can be readily obtained from suppliers that already have obtained FDA clearance to manufacture these components. We have developed a proprietary manufacturing process to create a uniform porous three-dimensional scaffolding structure for each device. We

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plan to purchase the raw material polymers from suppliers and then utilize our proprietary manufacturing process to create the final polymer scaffolding. Proprietary manufacturing processes will include batch processes to create the scaffolds. We intend to either establish a manufacturing facility or utilize a third-party to produce the polymer scaffolding and then package the final product.

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.

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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 16 employees, consisting of 12 full-time employees and 4 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 have not generated any revenue to date and, through December 31, 2011, have incurred net losses of approximately $47,817,000 since inception. It can be expected that we will continue to incur significant

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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 until 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 Practice 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

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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.

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.

We license our core technology from Children s Medical Center Corporation (CMCC) and Massachusetts Institute of Technology (MIT), and we could lose our rights to this license if a dispute with CMCC or MIT arises or if we fail to comply with the financial and other terms of the license.

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.

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.

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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.

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; Pre-Market Approval Application (PMA); and FDA approval of the 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.

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

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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.

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.

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We will be required to obtain international regulatory approval to market and sell our products outside of the United States.

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.

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.

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 affect on us.

There are a limited number of suppliers that can provide materials to 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.

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

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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 may have product liability exposure.

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.

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.

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

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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.

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.

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.

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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.

Our ability to raise capital as required may be difficult given the current condition of the capital and credit markets.

We are likely in the future to seek to access the capital markets for our capital needs. Traditionally, biotech companies have funded their research and development expenditures through raising capital in the equity markets. Declines and uncertainties in these markets over the past few years have severely restricted raising new capital and have affected companies ability to continue to expand or fund existing research and development efforts. 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, both in the United States and worldwide have deteriorated significantly and will adversely affect our access to capital and may increase the cost of capital. If these economic conditions continue or become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected.

We are dependent on 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. Although we presently do not maintain key person life insurance policies on any of our personnel, we are currently in the process of obtaining key man insurance on Frank Reynolds, our Chairman, Chief Executive Officer and Chief Financial Officer.

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

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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.

Compliance with the reporting requirements of federal securities laws can be expensive.

We are a public reporting company in the United States, and accordingly, subject to the information and reporting requirements of the Securities Exchange Act of 1934, as amended (the Exchange Act) and other federal securities laws, and the compliance obligations of the Sarbanes-Oxley Act. The costs of preparing and filing annual and quarterly reports and other information with the SEC and furnishing audited reports to stockholders are substantial.

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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;

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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.

Our officers and directors beneficially own approximately 31% of our outstanding shares of common stock. Such concentrated control of us may adversely affect the price of our common stock. Investors who acquire common stock may have no effective voice in the management of the Company. Sales by insiders or affiliates of the Company, along with any other market transactions, could affect the market price of our common stock.

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.

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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 the 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.

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Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

Our executive offices are located in leased premises at One Broadway, 14th Floor, Cambridge, MA 02142 and our phone number is 617-475-1520.

On November 15, 2010, we entered into a commercial lease for 1,200 square feet of office and laboratory space in Medford, MA for a two year period. On November 29, 2011 we executed a commercial lease for 20,917 square feet of office, laboratory and manufacturing space in Cambridge, MA for a period of six years and three months commencing June 2012.

Item 3. LEGAL PROCEEDINGS

From time to time we may be named in claims arising in the ordinary course of business. Currently, no legal proceedings, government actions, administrative actions, investigations or claims are pending against us or involve us that, in the opinion of our management, could reasonably be expected to have a material adverse effect on our business and financial condition.

We anticipate that we will expend significant financial and managerial resources in the defense of our intellectual property rights in the future if we believe that our rights have been violated. We also anticipate that we will expend significant financial and managerial resources to defend against claims that our products and services infringe upon the intellectual property rights of third parties.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

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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 the quarterly period ended December 31, 2011 based upon reports of transactions on the OTC Bulletin Board. Prices have been adjusted to reflect the forward split of our Common Stock that occurred on October 22, 2010.

Fiscal Quarter End	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
December 31, 2010	$ 4.00	$ 1.30

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 12, 2012, the closing bid price of our Common Stock as reported by the OTC Bulletin Board was $2.48 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.

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Record Holders

As of March 12, 2012, there are approximately 219 record holders of 63,781,404 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

Not applicable.

Item 6. SELECTED FINANCIAL DATA

Not required.

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

You should read the following discussion and analysis of financial condition and results of operations together 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, Special Note Regarding Forward-Looking Statements and elsewhere in this annual report.

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 conditio constructions (will, may, could, should, etc.), or similar expressions, identify certain of these forward-looking statements. These forward-lookin 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.

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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, 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 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,	
	2011	**2010**
Risk-free interest rate	0.97%-3.05%	1.63%-3.05%
Expected dividend yield	0%	0%
Expected term (employee grants)	6.25 years	6.25 years
Expected volatility	69%	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 Stock-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.

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Research and Development and General and Administrative Expenses

Research and development expenses consist primarily of 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, 2011 and 2010

Research and Development Expenses

Research and development expenses increased by $2,430,000 to approximately $4,103,000 for the year ended December 31, 2011 from approximately $1,673,000 for the year ended December 31, 2010. The increase in expenses is primarily attributable to the broadened portfolio of products, the hiring of additional personnel and an increase in costs associated with pre-clinical studies. In 2010 the Company received a $245,000 grant that was recorded as a reduction of research and development expenses.

General and Administrative Expenses

General and administrative expenses increased by $2,832,000 to approximately $4,556,000 for the year ended December 31, 2011 from approximately $1,724,000 for the year ended December 31, 2010. The increase in expenses is primarily attributable an increase in costs associated with operating as a public company and increases in rent salary and benefit costs.

Interest Expense

Interest expense decreased by $552,000 from $564,000 in 2010 to $13,000 in 2011. In 2010 the Company incurred $317,000 of non-cash interest expense from a bridge notes payable and $195,000 of interest expense for convertible notes payable. The bridge notes payable and the convertible notes payable were converted into common stock during 2010.

Derivatives Loss

Derivatives loss increased by $22,113,000 to $26,066,000 for the year ended December 31, 2011 from $3,953,000 for the year ended December 31, 2010. The increase in this non-cash expense is attributable to the increase in the fair value of the derivative warrant liability which is primarily related to the increase in the Company s stock price.

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, 2011, the accumulated deficit was $47,817,000 and the stockholders deficit was $31,160,000.

At December 31, 2011, we had total current assets of $5,016,000 and current liabilities of $36,740,000 resulting in a working capital deficit of $31,724,000. At December 31, 2011, the Company had total assets of $5,702,000 and total liabilities of $36,862,000, resulting in a stockholders deficit of $31,160,000.

In 2011, the Company used approximately $279,000 of cash to acquire property and equipment.

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Net cash used by operating activities for the year ended December 31, 2010 was $7,430,000. During 2011, the Company raised $2,999,000 from the issuance of common stock and received net proceeds of $152,000 from loans. In February 2012, the Company completed a firm underwritten 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 $20.0 million and $18.1 million of net proceeds after deducting the underwriter discount and offering expenses,

At December 31, 2011, the Company had cash of $4,364,000. The Company expects the cash on hand at December 31, 2011 together with the $18.1 million of net proceeds raised from the public offering completed in February 2012 will funds operations into 2014.

We will need to raise substantial additional capital to complete its clinical trials, obtain marketing approvals and commercialize its products.

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 15, 2010, the Company entered into a commercial lease for 1,200 square feet of office and laboratory space in Medford, MA. The term of this lease is for two years with monthly payments of approximately $3,900. On November 29, 2011, the Company entered into a commercial lease for 20,917 square feet of office, laboratory and manufacturing space in Cambridge, MA. The term of this lease is six years and three months, with one five-year extension option. Monthly payments of $76,696 commence on July 15, 2012. The terms of the lease required a standby letter of credit for the amount of $392,883 deposited with the commercial bank as security for the letter of credit.

Pursuant to the terms of the non-cancelable lease agreements in effect at December 31, 2011, future minimum rent commitments are as follows:

Year Ending December 31,	
2012	$ 311,574
2013	926,449
2014	947,366
2015	968,283
2016	989,200
2017 and thereafter	1,736,111
Total	$ 5,878,983

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required.

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Item 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Consolidated Financial Statements

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Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheets of InVivo Therapeutics Holdings Corp. as of December 31, 2011 and 2010, and the related consolidated statements of operations, changes in stockholders deficit and cash flows for the years then ended and for the period from November 28, 2005 (inception) to December 31, 2011. 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 consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated 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, 2011 and 2010, and the results of its operations and its cash flows for the periods then ended in conformity with U.S. generally accepted accounting principles.

/s/ Wolf & Company, P.C.

Boston, Massachusetts

March 14, 2012

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Consolidated Balance Sheets

	December 31, 2011	2010
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 4,363,712	$ 8,964,194
Restricted cash	547,883	
Prepaid expenses	104,022	81,166
Total current assets	5,015,617	9,045,360
Property and equipment, net	520,482	280,181
Other assets	166,139	53,639
Total assets	$ 5,702,238	$ 9,379,180
LIABILITIES AND STOCKHOLDERS DEFICIT:		
Current liabilities:		
Accounts payable	$ 567,195	$ 336,945
Loan payable-current portion	50,578	
Capital lease payable-current portion	30,724	
Derivative warrant liability	35,473,230	10,647,190
Accrued expenses	618,369	247,547
Total current liabilities	36,740,096	11,231,682
Loan payable-less current portion	83,794	
Capital lease payable-less current portion	38,042	
Total liabilities	36,861,932	11,231,682
Commitments and contingencies		
Stockholders deficit:		
Common stock, $0.00001 par value, authorized 200,000,000 and 100,000,000 shares at December 31, 2011 and December 31, 2010, respectively; issued and outstanding 53,760,471 and 51,647,171 shares at December 31, 2011 and 2010, respectively.	538	516
Additional paid-in capital	16,656,830	11,235,829
Deficit accumulated during the development stage	(47,817,062)	(13,088,847)
Total stockholders deficit	(31,159,694)	(1,852,502)
Total liabilities and stockholders deficit	$ 5,702,238	$ 9,379,180

See notes to consolidated financial statements.

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Consolidated Statements of Operations

	Years Ended December 31,		Period from November 28, 2005 (inception) to December 31, 2011
	2011	2010	
Operating expenses:			
Research and development	$ 4,102,847	$ 1,673,202	$ 8,883,834
General and administrative	4,555,872	1,724,102	8,251,537
Total operating expenses	8,658,719	3,397,304	17,135,371
Operating loss	(8,658,719)	(3,397,304)	(17,135,371)
Other income (expense):			
Other income			383,000
Interest income	8,759	3,379	20,049
Interest expense	(12,676)	(564,443)	(1,066,331)
Derivatives losses	(26,065,579)	(3,952,582)	(30,018,161)
Other income (expense), net	(26,069,496)	(4,513,646)	(30,681,443)
Net loss	$ (34,728,215)	$ (7,910,950)	$ (47,816,814)
Net loss per share, basic and diluted	$ (0.67)	$ (0.24)	$ (1.56)
Weighted average number of common shares outstanding, basic and diluted	51,894,871	33,367,239	30,707,308

See notes to the consolidated financial statements.

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Consolidated Statements of Changes in Stockholders Deficit

	Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders Deficit
	Shares	Amount			
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	3	209,448		209,451
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	1	10,433		10,434
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)

See notes to the consolidated financial statements.

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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, 2011
	2011	2010	
Cash flows from operating activities:			
Net loss	$ (34,728,215)	$ (7,910,950)	$ (47,816,814)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	144,662	44,878	237,627
Non-cash derivatives losses	26,065,579	3,952,582	30,018,161
Non-cash interest expense		528,535	962,834
Common stock issued to 401(k) plan	41,662		41,662
Common stock issued for services	209,451		209,451
Share-based compensation expense	921,512	664,908	1,800,352
Changes in operating assets and liabilities:			
Restricted cash	(547,883)		(547,883)
Prepaid expenses	(12,805)	(70,268)	(93,971)
Other assets	(125,000)		(200,000)
Accounts payable	230,250	255,770	567,195
Accrued interest payable		(67,931)	(15,256)
Accrued expenses	370,822	(46,037)	618,369
Net cash used in operating activities	(7,429,965)	(2,648,513)	(14,218,273)
Cash flows from investing activities:			
Purchases of property and equipment	(278,923)	(146,262)	(630,708)
Net cash used in investing activities	(278,923)	(146,262)	(630,708)
Cash flows from financing activities:			
Proceeds from issuance of convertible notes payable		200,000	4,181,000
Proceeds from convertible bridge notes		500,000	500,000
Principle payments on capital lease obligation	(24,774)		(24,774)
Proceeds from (repayment of) from loans payable	134,372	(590,985)	134,372
Proceeds from issuaance of common stock and warrants	2,998,808	11,423,287	14,422,095
Net cash provided by financing activities	3,108,406	11,532,302	19,212,693
(Decrease) increase in cash and cash equivalents	(4,600,482)	8,737,527	4,363,712
Cash and cash equivalents at beginning of period	8,964,194	226,667	
Cash and cash equivalents at end of period	$ 4,363,712	$ 8,964,194	$ 4,363,712
Supplemental disclosure of cash flow information and non-cash transactions:			
Cash paid for interest	$ 8,530	$ 34,204	$ 106,047

Conversion of convertible notes payable and accrued interest into common stock	$	$ 3,323,128	$ 4,672,484
Conversion of convertible bridge note payable and accrued interest into common stock	$	$ 504,597	$ 504,597
Asset acquired through capital lease obligation	$ 93,540	$	$ 93,540
Beneficial conversion feature on convertible and bridge notes payable	$	$ 272,762	$ 134,410
Fair value of warrants issued with bridge notes payable	$	$ 178,726	$ 178,726
Fair value of warrants issued in connection with loan agreement	$ 10,051	$	$ 10,051
Issuance of founders shares	$	$	$ 248
Reclassification of derivative warrant liability to additional paid-in capital	$ 1,239,539	$	$ 1,239,539

See notes to the consolidated financial statements.

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Notes to Consolidated Financial Statements

Years Ended December 31, 2011 and 2010, and the Period from

November 28, 2005 (Inception) through December 31, 2011

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. 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 ITHC a shell company with no assets or liabilities in order to facilitate the Merger. Although all transactions

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

NATURE OF OPERATIONS (continued)

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

As of December 31, 2011, the Company held approximately $4,364,000 in cash and cash equivalents. From time to time, the Company may have cash balances in financial institutions in excess of insurance limits. The Company has never experienced any losses related to these balances. All of the Company s non-interest bearing cash balances were fully insured at December 31, 2011 due to a temporary federal program in effect from December 31, 2010 through December 31, 2012. Under the program, there is no limit on the amount of insurance for eligible accounts. Beginning in 2013, insurance coverage will revert to $250,000 per depositor at each financial institution, and non-interest bearing cash balances may again exceed federally insured limits. The Company s cash equivalents are in money market funds and certificates of deposit. The cash and cash equivalents in interest-bearing accounts and non-interest bearing accounts ineligible under the program amounted to approximately $4,231,000 as of December 30, 2011.

Restricted cash

Restricted cash of $548,000 represents a $105,000 security deposit related to the Company s credit card account, a $50,000 minimum balance in a checking account that is required as part of a loan agreement, and a $393,000 standby letter of credit in favor of a landlord (see Note 18). This letter of credit expires December 22, 2012 and may be extended through July 31, 2023.

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

SIGNIFICANT ACCOUNTING POLICIES (continued)

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
Research and lab equipment	5 years

Depreciation expense for the years ended December 31, 2011 and 2010 was $132,162 and $39,878, 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. During 2010, the Company applied for a grant under the IRS Qualifying Therapeutic Discovery Project (QTDP) program. The application was approved and the Company received a grant for $244,500 under the program. This amount was recorded as a reduction in research and development expenses.

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, 2011 and 2010 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 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

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

SIGNIFICANT ACCOUNTING POLICIES (continued)

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, 2011 or 2010. Tax returns for all years are still open for examination.

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, 2011 and 2010.

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 Loss per Common Share

Basic and diluted net loss per share of Common Stock has been computed by dividing the net loss in each period by the weighted average number of shares of Common Stock outstanding during such period. For the periods presented, options, warrants and convertible securities were anti-dilutive and therefore excluded from diluted loss per share calculations.

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

SIGNIFICANT ACCOUNTING POLICIES (continued)

Recent Accounting Pronouncements

In May 2011, the FASB issued ASU 2011-04, Fair Value Measurement (Topic 820). The ASU provides amendments to achieve common fair value measurements and disclosure requirements in US GAAP and IFRS. The guidance clarifies and expands the disclosure pertaining to unobservable inputs used in Level 3 fair value measurements, including the disclosure of quantitative information related to (1) the valuation processes used, (2) the sensitivity of the fair value measurement to changes in unobservable inputs, and (3) use of a nonfinancial asset in a way that differs from the asset s highest and best use. The guidance also requires that public entities disclose the level within the fair value hierarchy for assets and liabilities not measured at fair value in the statement of financial position but for which the fair value is disclosed. The amendments are to be applied prospectively and are effective for annual periods beginning after December 15, 2011 for public companies. The Company does not expect the adoption to have a material impact.

3. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	December 31,	
	2011	2010
Computer software and hardware	$ 138,662	$ 91,057
Research and lab equipment	585,586	260,728
Less accumulated depreciation	(203,766)	(71,604)
	$ 520,482	$ 280,181

4. OTHER ASSETS

Other assets consist of patent licensing fees paid to license intellectual property (see Note 17). The Company is amortizing the license fee to research and development over its 15-year term.

	December 31,	
	2011	2010
Patent licensing fee	$ 200,000	$ 75,000
Accumulated amortization	(33,861)	(21,361)
	$ 166,139	$ 53,639

Amortization expense was $12,500 and $5,000 for the years ended December 31, 2011 and 2010, respectively. Amortization expense in each of the next five years is expected to be approximately $17,000 per year.

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

5. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	December 31, 2011	December 31, 2010
Other accrued expenses	$ 115,102	$ 45,053
Accrued payroll	358,144	179,629
Accrued vacation	145,123	22,865
	$ 618,369	$ 247,547

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.

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

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

	December 31, 2010			
	Level 1	Level 2	Level 3	Fair Value
Liabilities:				
Derivative warrant liability	$	$ 10,647,190	$	$ 10,647,190

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

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, 2011
Capital lease payable	$ 68,766
Less:current portion	(30,724)
	$ 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 year ended December 31, 2011, interest expense recorded on the capital lease was $3,987. For the year ended December 31, 2011, depreciation expense on the assets under capital lease was $22,761 and the net book value at December 31, 2011 amounted to $101,390.

8. LOAN PAYABLE

In June 2011, the Company entered into a loan agreement with a bank. The loan agreement provides the Company with a $1,000,000 line of credit for the purchase of capital equipment. The line is available to the Company until December 31, 2012. The annual interest rate is the greater of 6.75% or 3.50% above the Prime Rate. Borrowings are 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 will be amortized to interest expense over a three year period commencing from the date of the first draw from the equipment line of credit. Amortization of the deferred financing costs for the year ended December 31, 2011 was $4,146 and is included in interest expense. As of December 31, 2011, advances under the equipment line of credit totaled $151,733. The equipment line of credit is secured by substantially all the assets of the Company excluding intellectual property. In accordance with the agreement, the Company is required to maintain its primary banking and investments accounts with the commercial bank and a deposit of not less than $50,000 at the bank.

Loan payable consisted of the following:

	December 31, 2011
Equipment loan	$ 134,372
Less:current portion	(50,578)
	$ 83,794

Interest expense related to the loan payable in the year ended December 31, 2011 was $8,334. Principal payment due in the years ended December 31, 2012, 2013, and 2014 are $50,578, $50,578, and $33,216, respectively.

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

9. CONVERTIBLE NOTES PAYABLE

Since inception, the Company issued Convertible Notes Payable to investors totaling $4,181,000. In the year ended December 31, 2010, these notes provided cash proceeds of $200,000. The terms of the Convertible Notes Payable include interest at 8% and stipulated that the notes convert into shares of Common Stock upon the earlier of maturity of the notes or the completion of a Financing Round, a single financing or a series of related financings that raised a minimum of $4,000,000 or $5,000,000 depending on the terms of the individual notes. The notes convert at the offering price of such financing.

Certain of the notes entitled the holders to receive either a 10% or 20% discount on the conversion price if the notes were converted in connection with a Financing Round prior to the maturity date. The Company initially assessed whether a beneficial conversion feature existed on the issuance date based on the difference, if any, between the conversion price and the fair value of the Common Stock. The Company assumed the most favorable conversion price that would be in effect assuming no changes to the circumstances other than the passage of time. Based on this analysis, the Company concluded that there was no beneficial conversion feature at issuance.

However, the conversion terms are subject to change in the event of a Financing Round. Therefore, at the commitment date, the Company measured the contingent beneficial conversion feature based on the intrinsic value of the fixed percentage discount but such beneficial conversion feature was not recognized unless and until the triggering event occurs. This amount was determined by dividing the face amount of the convertible notes by the discount factor (0.90 or 0.80).

In March 2010, the Company completed a series of financings that met the definition of a Financing Round which accelerated the conversion of certain notes prior to their maturity dates triggering the discount provisions discussed above.

During the year ended December 31, 2010, the remaining outstanding Convertible Notes Payable of $3,040,000 and accrued interest payable of $288,128 converted into 3,792,417 shares of Common Stock in conjunction with the Financing Round. As of December 31, 2010, all of the Convertible Notes Payable had been converted into Common Stock.

As a result of the Financing Round in March 2010, the Company recorded the previously measured contingent beneficial conversion feature as a discount on the notes and additional paid-in capital. As the discount occurred simultaneously with the conversion of the notes, the discount was immediately charged to non-cash interest expense. Accordingly, during the year ended December 31, 2010, the Company recorded a beneficial conversion feature and related non-cash interest expense of $134,410.

Interest accrued on the outstanding balances at an annual rate of 8%. At the election of the Company, the accrued interest was to be paid in cash or in Common Stock at the time the notes were converted to Common Stock. For the year ended December 31, 2010, the Company accrued interest expense on the notes of $62,385.

10. BRIDGE NOTES PAYABLE

From July through September 2010, the Company raised $500,000 from the sale of 6% convertible promissory notes (the Bridge Notes). The Bridge Notes pay interest at 6% and had a stated maturity date of December 31, 2010. The Bridge Notes and all accrued interest were only convertible in the event of a Qualified Next Round Financing, as defined, at 100% of the price in that Qualified Next Round Financing. Otherwise, the Bridge Notes were to be repaid at their maturity date. In connection with the Bridge Notes,

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

BRIDGE NOTES PAYABLE (continued)

the Company also issued to Bridge Notes investors warrants to purchase 500,000 shares of Common Stock (the Bridge Warrants). The Bridge Warrants are exercisable for a period of five years with an exercise price of $1.00 per share.

In order to record the Bridge Notes and Bridge Warrants, the Company allocated the proceeds first to the fair value of the Bridge Warrants. The residual was then allocated to the Bridge Notes. As a result, the Company allocated $138,352 to the Bridge Warrants with the remainder of the proceeds allocated to the Bridge Notes. The total discount on the Bridge Notes of $138,352 was recognized as non-cash interest expense over the term of the Bridge Notes and was expensed to interest expense in 2010.

In order to determine if a beneficial conversion feature existed, the Company compared the effective conversion price of the Bridge Notes to the commitment date fair value of the Common Stock and determined a beneficial conversion feature in the amount of $138,352. However, since the Bridge Notes were only convertible in the event of a Qualified Next Round Financing, this was determined to be a contingent beneficial conversion feature not to be recognized unless and until the triggering event occurs.

In October 2010, the Company completed a private placement of Common Stock (see Note 11) which met the definition of a Qualified Next Round Financing. The Bridge Notes and accrued interest of $4,597 converted into 504,597 Units, with each unit consisting of one share of Common Stock and one warrant to purchase Common Stock at $1.40 per share. As a result of the Qualified Next Round Financing, the contingent beneficial conversion feature of $138,352 was recognized as a further discount on the Bridge Notes and additional paid-in capital on the date of conversion. Since the conversion took place simultaneously with the Qualified Next Round Financing, this discount of $138,352 was immediately charged to non-cash interest expense.

The Company engaged a registered broker-dealer as a placement agent (the Placement Agent) in conjunction with the Bridge Notes. As compensation, the Placement Agent received a warrant to purchase 100,000 shares of Common Stock at an exercise price of $1.00 per share. The fair value of the warrants issued to the Placement Agent of $40,373 was recorded as a debt issuance cost and amortized to non-cash interest expense over the term of the Bridge Notes.

For the year ended December 31, 2010, interest expense related to the Bridge Notes, including amortization of the discount and debt issuance costs, was $321,674.

The warrants issued to the Bridge Notes investors and the Placement Agent 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, and are therefore accounted for as derivative liabilities (see Note 13).

11. 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 valuation allowance against its deferred tax assets.

At December 31, 2011, the Company had Federal and Massachusetts net operating loss carryforwards of approximately $14,950,000 and $14,928,000, 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

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

INCOME TAXES (continued)

the expiration of net operating losses before utilization. The Company also had research and development tax credit carryforwards at December 31, 2011 of approximately $281,000 which will begin to expire in 2021 unless previously utilized.

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

	December 31,	
	2011	2010
Net operating loss carryforward	$ 5,896,441	$ 3,016,062
Research and development credit carryforward	257,110	120,316
Stock-based compensation	740,714	382,295
Deferred compensation		52,200
Charitable contributions	68,694	17,751
Subtotal	6,962,959	3,588,624
Valuation allowance	(6,962,959)	(3,588,624)
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, 2011 and 2010, the valuation allowance increased by $3,374,000 and $1,570,000 respectively.

The Company has no uncertain tax positions at December 31, 2011 and 2010 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,	
	2011	2010
Statutory rate	34.0%	34.0%
State taxes, net of benefit	1.4%	2.7%
Permanent differences:		
Derivative losses	-25.7%	-19.1%
Other	-0.2%	-0.2%
R&D tax credit	0.2%	0.7%

Increase in valuation reserve	-9.7%	-18.1%
	0.0%	0.0%

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

12. COMMON STOCK

The Company has authorized 200,000,000 shares of Common Stock, $0.00001 par value per share, of which 53,760,471 shares and 51,647,171 shares were issued and outstanding as of December 31, 2011 and 2010, respectively.

At inception in 2005, the Company issued its founders 24,787,080 shares of Common Stock with a par value of $248 for no consideration.

In 2009, the Company issued 1,472,435 shares of Common Stock to the holders of Convertible Notes Payable upon conversion of these notes. At the conversion dates, the principal balance of $1,141,000 and accrued interest payable of $203,366 were converted into Common Stock at a price of $0.91 per share.

In March 2010, the Company sold 1,095,258 shares of Common Stock to an investor at a price per share of $0.91 and the Company received cash proceeds of $1,000,000.

During the six months ended June 30, 2010, the Company issued 3,792,417 shares of Common Stock to the holders of Convertible Notes Payable upon the conversion of these notes. At the conversion date, the principal balance of $3,040,000 and accrued interest payable of $288,128 were converted into Common Stock. Certain notes provided for conversion at a discount to the $0.91 price (see Note 9).

On October 26, 2010, in conjunction with the Merger (see Note 1), the Company issued 6,999,981 shares of Common Stock to the former shareholders of ITHC.

In connection with the Merger on October 26, 2010 and in two subsequent closings in November and December 2010, the Company completed a private placement of 13,000,000 Units of its securities for total gross proceeds of $13,000,000 and net proceeds of $10,927,883 (the Offering). Included in these amounts are 504,597 Units and $504,597 related to the conversion of the Bridge Notes (see Note 10). Each Unit consisted of one share of Common Stock and a warrant to purchase one share of Common Stock exercisable at $1.40 per share (the Investor Warrants). In conjunction with the Merger and the Offering, the Company issued to an attorney 500,000 shares of its Common Stock with a fair value of $500,000. This was considered a stock issuance cost and was therefore recorded as both a debit and credit to additional paid-in capital.

In order to account for the Units, the Company allocated the proceeds between the Common Stock and warrants first to the fair value of the warrants with the residual allocated to the Common Stock. As a result, the Company allocated $4,475,791 to the warrants with the remainder of the proceeds allocated to the Common Stock. The fair value of the Placement Agent warrants, $2,040,091, was recorded as a warrant derivative liability and a stock issuance cost net against the gross proceeds received.

In October 2010, the Company issued 500,000 shares of Common Stock with a fair value of approximately $500,000 for legal services related to the Merger and related transactions. These shares were considered non-cash stock issuance costs and were recorded as a debit and credit to additional paid-in capital.

In connection with the Offering, the Company paid the Placement Agent a commission of 10% of the funds raised from such investors in the Offering. In addition, the Placement Agent received a non-accountable expense allowance equal to 3% of the proceeds raised in the Offering as well as warrants to purchase a number of shares of Common Stock equal to 20% of the number of common shares underlying Units sold to investors in the Offering. As a result of the foregoing arrangement, the Placement Agent was paid commissions and expenses of $1,690,000 and was issued warrants to purchase (i) 2,600,000 shares of Common Stock at an exercise price of $1.00 per share and (ii) 2,600,000 shares of Common Stock at an exercise price of $1.40 per share. Other cash expenses related to the private placement totaled $382,117.

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

COMMON STOCK (continued)

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 $3.06 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, 2011, the Company had the following reserves established for the future issuance of Common Stock as follows:

Reserves for the exercise of warrants	18,405,975
Reserves for the exercise of stock options	7,879,005
Total Reserves	26,284,980

13. DERIVATIVE INSTRUMENTS

Certain warrants issued to the investors in the Offering, the Bridge Note investors and the Placement Agent (see notes 10 and 12) 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 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, 2011 and 2010 was $35,473,230 and $10,647,190, respectively and are 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 losses are non-cash expenses and for the years ended December 31, 2011 and 2010 $26,065,579 and $3,952,582, respectively were included in other income (expense) in the consolidated statement of operations.

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

	As of December 31,	
	2011	2010
Risk free interest rate	.52-.58%	2.0%
Expected dividend yield	0%	0%
Contractual term	3.7-3.9 years	4.7-4.9 years
Expected volatility	79%	50%

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

DERIVATIVE INSTRUMENTS (continued)

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, 2011 and 2010:

	Years Ended December 31,	
	2011	2010
Balance at beginning of year	$ 10,647,190	$
Warrants intially recorded as derivative liability		6,694,608
Increase in the fair value of the warrants	26,065,579	3,952,582
Reduction in derivative liability due to exercise of warrants	(1,239,539)	
Balance at end of year	$ 35,473,230	$ 10,647,190

14. 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, 2011, there were options to purchase an aggregate of 4,379,005 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 the 2010 Equity Incentive Plan, (the 2010 Plan). The Company s shareholders approved the 2010 Plan, as amended, on August 3, 2011. 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, 2011, the number of shares authorized for issuance under the 2010 Plan was 3,500,000 shares. As of December 31, 2011, there were options to purchase an aggregate of 2,003,888 shares of Common Stock outstanding under the 2010 Plan and 1,492,112 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.

Share-based compensation

For stock options issued and outstanding for the years ended December 31, 2011 and 2010, the Company recorded non-cash, stock-based compensation expense of $921,512 and $664,908, 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 (generally

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

STOCK OPTIONS (continued)

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,	
	2011	2010
Risk-free interest rate	0.97%-3.05%	1.63%-3.05%
Expected dividend yield	0%	0%
Expected term (employee grants)	6.25 years	6.25 years
Expected volatility	69%	49%

A summary of option activity under the Plans and options granted to officers of the Company outside any plan as of December 31, 2011 and changes for the year then ended is presented below:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2010	6,195,557	$ 0.59		
Granted	1,718,888	$ 1.52		
Forfeited	(1,467,821)	$ 1.00		
Exercised	(143,731)	$ 0.07		
Outstanding at December 31, 2011	6,302,893	$ 0.76	7.69	$ 12,520,372
Vested at December 31, 2011	3,366,302	$ 0.37	6.50	$ 8,025,166

The weighted average grant-date fair value of options granted during years ended December 31, 2011 and 2010 was $1.14 and $0.55 per share, respectively. The total fair value of options that vested in years ended December 31, 2011 and 2010 was $1,324,325 and $962,810, respectively. As of December 31, 2011, there was approximately $2,239,247 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 3.25 years at December 31, 2011.

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 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 determined upon grant that the vesting of the 30,000 shares is probable and the fair value of these shares at $23,400 is being amortized over an eight month period from September 2011 through April 2012. The Company has determined that vesting of the 50,000 shares is not probable at

this time. For the year ended December 31, 2011 the Company amortized $11,700 of stock compensation expense related to this grant.

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

15. WARRANTS

The following presents information about warrants to purchase Common Stock issued and outstanding at December 31, 2011:

Year Issued	Classification	Number of Warrants	Exercise Price	Date of Expiration
2010	Derivative	14,929,733	$ 1.40	10/26/2015-12/3/2015
2010	Derivative	3,117,034	$ 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
Total		18,405,975		
Weighted average exercise price			$ 1.39	
Weighted average life in years				3.9

16. 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 year ended December 31, 2011, the Company made a matching contribution in the form of the issuance of Company common stock. In the fourth quarter of 2011 the Company issued 39,848 shares of common stock and the fair value of $41,662 was recorded as expense in the Statement of Operations.

17. 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).

18. COMMITMENTS AND CONTINGENCIES

Operating Lease

On November 15, 2010, the Company entered into a commercial lease for 1,200 square feet of office and laboratory space in Medford, MA. The term of this lease is for two years with monthly payments of approximately $3,900. On November 29, 2011, the Company entered into a commercial lease for 20,917 square feet of office, laboratory and manufacturing space in Cambridge, MA. The term of this lease is six years and three months, with one five-year extension option. Monthly payments of $76,696 commence on July 15, 2012.

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InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

COMMITMENTS AND CONTINGENCIES (continued)

The terms of the lease required a standby letter of credit for the amount of $392,883 deposited with the commercial bank as security for the letter of credit (see Note 4).

Pursuant to the terms of the non-cancelable lease agreements in effect at December 31, 2011, future minimum rent commitments are as follows:

Year Ending December 31,	
2012	$ 311,574
2013	926,449
2014	947,366
2015	968,283
2016	989,200
2017 and thereafter	1,736,111
Total	$ 5,878,983

Total rent expense for the years ended December 31, 2011 and 2010, including month-to-month leases, was approximately $357,000 and $270,000, respectively.

19. SUBSEQUENT EVENTS

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

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 $20.0 million and $18.1 million of net proceeds after deducting the underwriter discount and offering expenses.

On March 5, 2012, in conjunction with an amended and restated employment agreement, the Chief Executive Officer was granted an option to purchase 590,000 shares of common stock at an exercise price of $2.68 per share, the fair value on the date the employment agreement was executed. The option has a ten year life and vests monthly over a period of forty eight months. Stock compensation expense of approximately $850,000 will be amortized over the forty eight month vesting period.

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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, 2011, 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, 2011 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, 2011.

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

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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

During the fiscal quarter ended December 31, 2011, 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.

Item 9B. OTHER INFORMATION

None.

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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 2012 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 2012 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 2012 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 2012 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 2012 Annual Meeting of Stockholders.

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PART IV

Item 15. EXHIBITS, 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.

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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 15, 2012

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 15, 2012*
/s/ George Nolen *George Nolen*	*Director*	*March 15, 2012*
/s/ Christi M. Pedra *Christi M. Pedra*	*Director*	*March 15, 2012*
/s/ Richard J. Roberts *Richard J. Roberts*	*Director*	*March 15, 2012*
/s/ Adam K. Stern *Adam K. Stern*	*Director*	*March 15, 2012*

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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, 2011, as filed with the SEC on November 14, 2011).
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 March 15, 2011).
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 Bridge Promissory Note of InVivo Therapeutics Corporation (incorporated by reference from Exhibit 4.2 to the Company s Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
4.3	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).
4.4(i)	Form of Warrant of InVivo Therapeutics Holdings Corp. ($1.00 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.)
4.4(ii)	Form of Warrant of InVivo Therapeutics Holdings Corp. ($1.40 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.)
4.5	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).
4.6	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.)
4.7	Warrant dated June 17, 2011 issued to Square 1 Bank.
4.8	Specimen Common Stock Certificate.
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).

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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).

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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).

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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.