

INVIVO THERAPEUTICS HOLDINGS CORP.

Form S-1

December 16, 2011

Table of Contents

As filed with the Securities and Exchange Commission on December 16, 2011

Registration No. 333-

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM S-1**  
**REGISTRATION STATEMENT**

*UNDER*

*THE SECURITIES ACT OF 1933*

**INVIVO THERAPEUTICS HOLDINGS CORP.**

(Exact Name of Registrant as Specified in Its Charter)

Nevada  
(State or other Jurisdiction of  
Incorporation or Organization)

3841  
(Primary Standard Industrial  
Classification Code Number)

36-4528166  
(I.R.S. Employer  
Identification Number)

Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form S-1

One Broadway, 14<sup>th</sup> Floor Cambridge, MA 02142 (617) 475-1520

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Frank M. Reynolds Chief Executive Officer One Broadway, 14<sup>th</sup> Floor Cambridge, MA 02142 (617) 475-1520

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

*Copies to:*

Thomas B. Rosedale, Esq. BRL Law Group LLC 425 Boylston Street 3<sup>rd</sup> Floor Boston, MA 02116 (617) 399-6931

**Approximate date of commencement of proposed sale to the public:** Promptly after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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.:  
Large accelerated filer   
Accelerated filer  (Do not check if a smaller reporting company)

Non-accelerated filer   
Smaller reporting company

**CALCULATION OF REGISTRATION FEE**

Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form S-1

| Title of Each Class of<br>Securities to be Registered | Proposed<br>Maximum<br>Aggregate<br>Offering Price(1) | Amount of<br>Registration Fee(2) |
|---|---|----------------------------------|
| Common Stock, \$0.00001 par value per Share           |   |                                  |
| Warrants to purchase shares of Common Stock(3)        |   |                                  |
| Common Stock issuable upon exercise of the warrants   |   |                                  |
| Total   | \$10,000,000  | \$1,146                          |

- (1) Pursuant to Rule 416 under the Securities Act, this registration statement also covers such indeterminate number of additional shares of common stock as may be issuable with respect to the shares being registered hereunder as a result of any stock splits, stock dividends or similar transactions.
- (2) Calculated pursuant to Rule 457(o) of the rules and regulations under the Securities Act of 1933.
- (3) The securities registered also include such indeterminate number of shares of common stock as may be issued upon exercise of warrants pursuant to the anti-dilution provisions of the warrants.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.**

**Table of Contents**

**The information contained in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

**Subject to Completion, Dated December 16, 2011**

**INVIVO THERAPEUTICS HOLDINGS CORP.**

**[ ] Shares of Common Stock**

**Warrants to Purchase up to [ ] Shares of Common Stock**

**and**

**[ ] Shares of Common Stock Underlying Warrants**

We are offering [ ] shares of our common stock and warrants. Each investor investing \$[ ] or more will receive [ ] warrants to purchase an aggregate of up to [ ] shares of common stock at a price of \$[ ] per share. We are not required to sell any specific dollar amount or number of shares of common stock or warrants, but will use our best efforts to sell all of the shares of common stock and warrants being offered. The offering expires on the earlier of (i) the date upon which all of the shares of common stock and warrants being offered have been sold, or (ii) , 2011.

Our common stock is currently available for trading in the over-the-counter market and is quoted on the OTC Bulletin Board under the symbol NVIV . The last sale price of our common stock on December 15, 2011 was \$2.04.

**These are speculative securities. Investing in our securities involves significant risks. You should purchase these securities only if you can afford a complete loss of your investment. See Risk Factors beginning on page 5.**

|  | Per Share | Total |
|--|-----------|-------|
| Public Offering Price                  | \$        | \$    |
| Underwriting Discounts and Commissions | \$        | \$    |
| Offering Proceeds before expenses      | \$        | \$    |

We estimate the total expenses of this offering will be approximately \$[ ]. Because there is no minimum offering amount required as a condition to closing in this offering, the actual public offering amount and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering set forth above. We have no current arrangements nor have we entered into any agreements with any underwriters, broker-dealers or selling agents for the sale of the securities, but we plan on entering into such arrangements and agreements. If we can engage one or more underwriters, broker-dealers or selling agents and enter into any such arrangement(s), the securities will be sold through such licensed underwriter(s), broker-dealer(s) and/or selling agent(s). See Plan of Distribution beginning on page 55 of this prospectus for more information on this offering.

This offering will terminate on , 2011, unless the offering is fully subscribed before that date or we decide to terminate the offering prior to that date. In either event, the offering may be closed without further notice to you. All costs associated with the registration will be borne by us. As there is no minimum purchase requirement, no funds are required to be escrowed and all net proceeds will be available to us at closing

Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form S-1

for use as set forth in Use of Proceeds beginning on page 18.

**NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.**

The shares of Common Stock may be sold directly by us to investors or through our underwriters, broker-dealers or selling agents. See Plan of Distribution .

**The date of this prospectus is .**

**Table of Contents**

**TABLE OF CONTENTS**

|  | <b>Page</b> |
|--|-------------|
| <u>PROSPECTUS SUMMARY</u>  | 1           |
| <u>RISK FACTORS</u>  | 5           |
| <u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>                                     | 18          |
| <u>USE OF PROCEEDS</u>   | 18          |
| <u>DIVIDEND POLICY</u>   | 18          |
| <u>DILUTION</u>  | 19          |
| <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u> | 20          |
| <u>BUSINESS</u>  | 25          |
| <u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT</u>                        | 36          |
| <u>DIRECTORS AND EXECUTIVE OFFICERS</u>  | 37          |
| <u>NON-EXECUTIVE OFFICER AND SCIENTIFIC AND BUSINESS ADVISORY BOARDS</u>                     | 39          |
| <u>EXECUTIVE COMPENSATION</u>  | 41          |
| <u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS</u>  | 49          |
| <u>MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS</u>                              | 51          |
| <u>DESCRIPTION OF SECURITIES</u>   | 52          |
| <u>PLAN OF DISTRIBUTION</u>  | 55          |
| <u>LEGAL MATTERS</u>   | 56          |
| <u>EXPERTS</u>   | 56          |
| <u>WHERE YOU CAN FIND MORE INFORMATION</u>   | 56          |
| <u>FINANCIAL STATEMENTS</u>  | F-1         |
| <u>PART II: INFORMATION NOT REQUIRED IN THE PROSPECTUS</u>                                   | II-1        |

**You should rely only on the information contained in this document or to which we have referred you. We have not authorized anyone to provide you with information that is different. This document may only be used where it is legal to sell these securities. The information contained in this document may only be accurate on the date of this document.**

**Prior to the offering to which this prospectus relates, we commenced and abandoned a private offering in which we sought to raise up to approximately \$10 million in proceeds from the sale of our securities. The private offering was made solely to persons or entities whom we believed to be accredited investors. We abandoned the private offering on December 9, 2011. We did not accept any offers to buy or indications of interest in the private offering. This prospectus supersedes any offering materials used in the private offering.**

**Table of Contents**

**PROSPECTUS SUMMARY**

*The following summary highlights selected information contained in this prospectus. This summary does not contain all the information that may be important to you. You should read the more detailed information contained in this prospectus, including but not limited to, the risk factors beginning on page 5. References to we, us, our, or the Company refer to InVivo Therapeutics Holdings Corp., together, with its consolidated subsidiaries where applicable. The term ITHC refers to InVivo Therapeutics Holdings Corp. (f/k/a Design Source, Inc.), the Nevada corporation, before giving effect to the Merger, and the term InVivo refers to InVivo Therapeutics Corporation, the Delaware corporation, before giving effect to the Merger.*

**History**

InVivo Therapeutics Corporation ( InVivo ) was incorporated on November 28, 2005 under the laws of the State of Delaware. On October 26, 2010, InVivo completed a reverse merger transaction (the Merger ) with InVivo Therapeutics Holdings Corporation (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 par value \$0.00001 per share (the Common Stock ) to the holders of InVivo common stock on October 26, 2010 on a 13.7706 for 1 basis in exchange for the 2,261,862 outstanding common shares of InVivo. All of the issued and outstanding options to purchase shares of InVivo common stock, and the issued and outstanding bridge warrants to purchase shares of InVivo common stock, converted, respectively, into options and new bridge warrants (the New Bridge Warrants ) to purchase shares of our Common Stock.

The Merger was a reverse merger, and InVivo is deemed to be the acquirer and ongoing operating company. The Merger was recorded as a recapitalization of InVivo, 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 are 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.

Simultaneously with the closing of the Merger on October 26, 2010, 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 ). In connection with the Split-Off, 14,747,554 shares of our Common Stock held by Peter Reichard, Lawrence Reichard and Peter Coker (the Split-Off Shareholders ) were surrendered and cancelled without further consideration, other than the shares of DSSC. An additional 1,014,490 shares of our Common Stock were cancelled by a shareholder for no additional consideration. 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 ITHC before the Merger.

In connection with the Merger, on October 26, November 10 and December 3, 2010, we completed a private placement (the 2010 Private Placement ) of 13,000,000 units of our securities, consisting of one share of Common Stock and a warrant to purchase one share of Common Stock (the Investor Warrants ). Prior to the Merger, InVivo completed a bridge financing, wherein it sold \$500,000 in principal amount of its bridge notes and 36,310 bridge warrants to accredited investors. Spencer Trask Ventures, Inc. ( Spencer Trask ) acted as placement agent in both the 2010 Private Placement and the bridge financing. We issued warrants to Spencer Trask as part of both of these transactions.

Please see Description of Capital Stock on page 52 for a reconciliation of the outstanding shares of InVivo and ITHC common stock on a pre and post Merger basis.

## Table of Contents

### **Business Overview**

InVivo was founded in 2005 to develop and commercialize new technologies for the treatment of spinal cord injuries. InVivo's proprietary technology was co-invented by Robert S. Langer, ScD, Professor at Massachusetts Institute of Technology 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 Massachusetts Institute of Technology (MIT).

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.

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. The Company expects 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.

The Company's 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.

The Company 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, the Company must submit an Investigational Device Exemption application (IDE) to the FDA and the FDA must approve the IDE. The Company submitted an IDE application for its biopolymer scaffolding device to the FDA on July 7, 2011. 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 Company plans to first conduct a pilot study in ten acute spinal cord patients followed by a larger pivotal study. The completion



**Table of Contents**

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 the Company is unable to raise additional capital to continue to fund the Company. Please see **Risk Factors** beginning on page 5 for a more detailed discussion of these risks.

If the product is approved by the FDA, the Company will need to expand manufacturing capacity, and establish sales, marketing and distribution channels to sell the product. The Company intends 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 expected to be regulated as a Class III medical device by the FDA. The product has been evaluated in animal studies and the Company submitted an Investigational Device Exemption with the FDA on July 7, 2011 that if approved by the FDA will permit the commencement of human clinical studies.

The biocompatible hydrogel for the local release of methylprednisolone to treat acute spinal cord and peripheral nerve 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.

At December 31, 2010, the Company had total assets of \$9,379,000 and total liabilities of \$11,232,000, resulting in a stockholders' deficit of \$1,853,000. At September 30, 2011, the Company had total assets of approximately \$4,604,000 and total liabilities of approximately \$5,194,000, resulting in a stockholders' deficit of \$590,000. At September 30, 2011, the Company had incurred net losses of approximately \$12,670,000 since inception.

**The Offering**

|  |   |
|--|---|
| <b>Securities Offered</b>                    | [     ] shares of common stock  |
|  | Warrants to purchase up to [     ] shares of common stock             |
|  | [     ] shares of common stock issuable upon exercise of the warrants |
| <b>Common stock outstanding as of</b>        | 52,730,582 shares   |
| <b>December 9, 2011</b>                      |   |
| <b>Common stock to be outstanding after</b>  | [     ] shares  |
| <b>the offering assuming the sale of all</b> |   |
| <b>shares covered hereby and assuming</b>    |   |
| <b>no exercise of the warrants for the</b>   |   |
| <b>shares covered by this prospectus</b>     |   |
| <b>Common stock to be outstanding after</b>  | [     ] shares  |
| <b>the offering assuming the sale of all</b> |   |

**shares covered hereby and assuming  
the exercise of all warrants for the  
shares covered by this prospectus**

**Table of Contents**

**Use of proceeds**

We estimate that we will receive up to \$[ ] in net proceeds from the sale of the securities in this offering, based on a price of [\$ ] per unit, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We will use the proceeds from the sale of the securities for research and development, working capital needs, capital expenditures and other general corporate purposes. See Use of Proceeds for more information.

**Risk factors**

The shares of common stock offered hereby involve a high degree of risk. See Risk Factors beginning on page 5.

**Dividend policy**

We currently intend to retain any future earnings to fund the development and growth of our business. Therefore, we do not currently anticipate paying cash dividends on our common stock.

**Trading Symbol**

Our common stock currently trades on the OTCQB Bulletin Board under the symbol NVIV.

Our principal business office is located at One Broadway, 14<sup>th</sup> Floor, Cambridge, Massachusetts 02142, and our telephone number is (617) 475-1520. Our website address is [www.invivotherapeutics.com](http://www.invivotherapeutics.com). Information contained on our website or any other website does not constitute part of this prospectus.

We will bear the expenses of registering these securities. See Plan of Distribution.

We had 52,730,582 shares of Common Stock issued and outstanding as of December 9, 2011. Unless the context indicates otherwise, all share and per-share Common Stock information in this prospectus:

excludes 4,379,006 shares underlying outstanding options under our 2007 Stock Incentive Plan; and

excludes 1,710,000 shares underlying outstanding options under our 2010 Equity Incentive Plan.

---

**Table of Contents**

**RISK FACTORS**

*If you purchase our securities, you will assume a high degree of risk. In deciding whether to invest, you should carefully consider the following risk factors, as well as the other information contained elsewhere in this prospectus. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations or prospects and cause the value of our securities to decline, which could cause you to lose all or part of your investment.*

**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 September 30, 2011, have incurred net losses of approximately \$12,670,000 since inception. It can be expected that we will continue to incur significant operating expenses and continue to experience losses in the foreseeable future. As a result, we cannot predict when, if ever, we might achieve profitability and cannot be certain that we will be able to sustain profitability, if achieved.

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

The development and approval to market and sell our product candidates will require a commitment of substantial funds, in excess of our current capital resources. Before we can market or sell any of our products, we will need to conduct costly and time-consuming research, which will include preclinical and clinical testing and regulatory approvals. We anticipate the amount of operating funds that we use will continue to increase along with our operating expenses over at least the next several years as we plan to bring our products to market. While we believe our current capital resources will satisfy our planned capital needs for at least 12 months, 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;



**Table of Contents**

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. To the extent we raise additional capital through the sale of equity securities, the ownership position of our existing stockholders could be substantially diluted. If additional funds are raised through the issuance of preferred stock or debt securities, these securities are likely to have rights, preferences and privileges senior to our Common Stock. Fluctuating interest rates could also increase the costs of any debt financing we may obtain.

***Our products will represent new and rapidly evolving technologies.***

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

## Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form S-1

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.

## **Table of Contents**

### ***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.

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,



## **Table of Contents**

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 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.

## **Table of Contents**

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.

*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

## **Table of Contents**

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 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.

## **Table of Contents**

### ***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 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.

## **Table of Contents**

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.

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

## **Table of Contents**

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

In order to approve a person's account for transactions in penny stocks, the broker or dealer must obtain financial information and investment experience objectives of the person; and make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form sets forth the basis on which the broker or dealer made the suitability determination; and that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

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

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.

## **Table of Contents**

***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.

***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 ITHC, there can be no assurance that we will not be liable for any or all of such liabilities. Any such liabilities of ITHC 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.

## **Table of Contents**

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

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

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

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

actual or anticipated variations in our operating results;

announcements of developments by us or our competitors;

the timing of IDE approval, the completion and/or results of our clinical trials;

regulatory actions regarding our products;

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

adoption of new accounting standards affecting our industry;

additions or departures of key personnel;

introduction of new products by us or our competitors;

sales of our Common Stock or other securities in the open market; and

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

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

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

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



## Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form S-1

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 Markets.

## **Table of Contents**

### ***Our Common Stock is controlled by insiders.***

Our officers and directors beneficially own approximately 35% 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.

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.

**Table of Contents**

*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.

*The Investor Warrants may be redeemed on short notice, which may have an adverse effect on the Common Stock price.*

We may redeem the Investor 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 our Investor Warrants will be forced to sell or exercise the Investor 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 our warrants to sell or exercise the Investor Warrants they hold.

*While the Investor and New Bridge Warrants are outstanding, it may be more difficult to raise additional equity capital.*

During the term that the Investor Warrants and New Bridge 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, the New Bridge 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.

**Table of Contents**

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus 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, intend, expects, plans, goals, projects, anticipates, believes, estimates, predicts, potential, or continue or the negative of these terms or 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 prospectus 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 prospectus. These cautionary statements should be considered with any written or oral forward-looking statements that we may issue in the future. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to reflect actual results, later events or circumstances or to reflect the occurrence of unanticipated events.

**USE OF PROCEEDS**

We estimate that we will receive up to \$[ ] in net proceeds from the sale of the securities in this offering, based on a price of \$[ ] per unit and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We will use the proceeds from the sale of the securities for research and development, working capital needs, capital expenditures and other general corporate purposes.

Pending any ultimate use of any portion of the proceeds from this offering, we intend to invest the proceeds in a variety of capital preservation investments, including short-term, interest-bearing instruments such as United States government securities and municipal bonds.

If a warrant holder exercises his warrants, we will also receive proceeds from the exercise of warrants. We cannot predict when, or if, the warrants will be exercised. It is possible that the warrants may expire and may never be exercised.

**DIVIDEND POLICY**

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.

**Table of Contents****DILUTION**

Dilution represents the difference between the offering price and the net tangible book value per share immediately after completion of this offering. Net tangible book value is the amount that results from subtracting total liabilities and intangible assets from total assets. Dilution of the value of the shares you purchase is a result of the lower book value of the shares held by our existing stockholders.

At \_\_\_\_\_, 2011, the net tangible book value of our shares of Common Stock was \$[ ] or approximately \$[ ] per share based upon 52,730,582 shares outstanding. After giving effect to our sale of [ ] shares of Common Stock at a public offering price of \$[ ] per share, and after deducting underwriting discounts and commissions and estimated offering expenses, our pro forma net tangible book value as of \_\_\_\_\_, 2011 would have been \$[ ], or \$[ ] per share. This represents an immediate increase in net tangible book value of \$[ ] per share to existing stockholders and an immediate dilution in net tangible book value of \$[ ] per share to purchasers of securities in this offering, as illustrated in the following table:

|   |    |
|---|----|
| Assumed initial public offering price per share                             | \$ |
| Pro forma net tangible book value per share as of _____, 2011               | \$ |
| Increase per share attributable to new investors                            |    |
| Pro forma as adjusted net tangible book value per share after this offering |    |
| Dilution per share to new investors in this offering                        | \$ |

The above discussion does not include the following:

1,690,000 shares of Common Stock reserved for future issuance under our equity incentive plans. As of September 30, 2011, there were 5,239,006 options outstanding under such plans with a weighted average exercise price of \$0.57 per share;

18,816,071 shares of Common Stock issuable upon exercise of outstanding warrants as of September 30, 2011, with exercise prices ranging from \$1.00 per share to \$1.40 per share;

[ ] shares of Common Stock issuable upon exercise of warrants at an exercise price of \$[ ] per share sold as part of this offering.

## **Table of Contents**

### **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 prospectus. 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 prospectus.*

As the result of the Merger and the change in business and operations of the Company from a shell company to a biotechnology company, a discussion of the past financial results of ITHC is not pertinent, and the financial results of InVivo, the acquirer and ongoing operating company, are considered the financial results of the Company on a historical and going-forward basis.

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

The discussion and analysis of the Company's financial condition and results of operations are based on the Company's financial statements, which the Company has prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires the Company 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, the Company evaluates such estimates and judgments, including those described in greater detail below. The Company bases its estimates on historical experience and on various other factors that the Company 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.

#### ***Critical Accounting Policies and Estimates***

Our consolidated financial statements, which appear at page F-1, have been prepared in accordance with accounting principles generally accepted in the United States, which require that the Company 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.

**Table of Contents****Stock-Based Compensation**

Stock options are generally granted with an exercise price at 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 Board of Directors.

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 the Company's Common Stock has been determined based on a number of factors including the stage of development of the Company, the value of the Company's Common Stock sold to outside investors and the market value of other medical device companies in a similar stage of development.

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. The Company uses 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:

|                                 | September 30,<br>2011 | December 31,<br>2010 | 2009       |
|---------------------------------|-----------------------|----------------------|------------|
| Risk-free interest rate         | 1.89%                 | 1.63% - 3.05%        | 2.68%      |
| Expected dividend yield         | 0%                    | 0%                   | 0%         |
| Expected term (employee grants) | 6.21 years            | 6.25 years           | 6.25 years |
| Expected volatility             | 67%                   | 49.12%               | 50.10%     |

**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.

**Results of Operations**

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.

## **Table of Contents**

### ***Comparison of three months ended September 30, 2011 and 2010***

#### **Research and Development Expenses**

Research and development expenses increased by \$692,000 to approximately \$1,017,000 for the three months ended September 30, 2011 from approximately \$325,000 for the three months ended September 30, 2010. The increase in expenses is primarily attributable to the hiring of additional personnel and an increase in costs of pre-clinical studies.

#### **General and Administrative Expenses**

General and administrative expenses increased by \$773,000 to approximately \$1,197,000 for the three months ended September 30, 2011 from approximately \$424,000 for the three months ended September 30, 2010. The increase in expenses is primarily attributable to 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 \$37,000 to zero for the three months ended September 30, 2011 from approximately \$37,000 for the three months ended September 30, 2010. The decrease in interest expense is due to the conversion into common stock of the remaining balance of the convertible notes payable as of September 30, 2010.

#### **Derivatives Gain (Loss)**

Derivatives gain (loss) was approximately \$5,276,000 and (\$51,000) for the three months ended September 30, 2011 and 2010, respectively, and reflects primarily the decrease in the fair value of the underlying common stock during the period.

### ***Comparison of nine months ended September 30, 2011 and 2010***

#### **Research and Development Expenses**

Research and development expenses increased by \$2,095,000 to \$3,045,000 for the nine months ended September 30, 2011 from approximately \$950,000 for the nine months ended September 30, 2010. The increase in expenses is primarily attributable to the hiring of additional personnel and an increase in costs of pre-clinical studies.

#### **General and Administrative Expenses**

General and administrative expenses increased by \$2,121,000 to approximately \$3,096,000 for the nine months ended September 30, 2011 from approximately \$975,000 for the nine months ended September 30, 2010. The increase in expenses is primarily attributable to 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 \$278,000 to approximately \$7,000 for the nine months ended September 30, 2011 from approximately \$285,000 for the nine months ended September 30, 2010. The decrease in interest expense is due to the conversion into common stock of the remaining balance of the convertible notes payable as of September 30, 2010.



## **Table of Contents**

### **Derivatives Gain (Loss)**

Derivatives gain (loss) was approximately \$6,560,000 and (\$51,000) for the nine months ended September 30, 2011 and 2010, respectively, and reflects primarily the decrease in the fair value of underlying common stock during the period.

### ***Comparison of the years ended December 31, 2010 and 2009***

#### **Research and Development Expenses**

Research and development expenses decreased by \$135,000, from \$1,808,000 in 2009 to \$1,673,000 in 2010. The decrease is primarily attributable to a reduction in costs of pre-clinical studies offset by stock compensation expense incurred in 2010 of \$376,000. In addition, during 2010 the Company received approximately \$245,000 as a grant under the IRS Qualifying Therapeutic Discovery Project (QTDP) program. This amount has been recorded as a reduction in research and development expenses.

#### **General and Administrative Expenses**

General and administrative expenses increased by \$888,000, from \$836,000 in 2009 to \$1,724,000 in 2010. The increase is primarily attributable to an increase in stock compensation expense of \$118,000, approximately \$120,000 of costs incurred in the fourth quarter of 2010 associated with operating as a public company, and increases in rent, salary and benefit costs.

#### **Interest expense**

Interest expense increased by \$308,000 from \$256,000 in 2009 to \$564,000 in 2010. The increase is primarily attributable to non-cash interest expense of \$317,000 associated with the \$500,000 bridge note financing in 2010.

#### **Other Income**

Other income in 2009 of \$383,000 resulted from a legal settlement. There was no other income in 2010.

#### **Derivatives Loss**

Derivatives loss totaled \$3,953,000 for the year ended December 31, 2010 and reflects the change in the fair value of derivative warrant liabilities during the year. We did not have a derivative warrant liability or derivative (gain) loss in 2009.

#### **Financial Condition, Liquidity and Capital Resources**

Since inception, we have devoted substantially all of our 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, we have experienced negative cash flows from operations. We have financed our operations primarily through the sale of equity-related securities. At September 30, 2011, the accumulated deficit was approximately \$12,670,000 and the stockholders' deficit was approximately \$590,000.

At September 30, 2011, we had total current assets of approximately \$3,961,000 and current liabilities of approximately \$5,075,000 resulting in a working capital deficit of approximately \$1,114,000. At September 30, 2011, we had total assets of approximately \$4,604,000 and total liabilities of approximately \$5,194,000, resulting in a stockholders' deficit of \$590,000.

**Table of Contents**

Net cash used by operating activities for the nine months ended September 30, 2011 was approximately \$5,146,000. We spent approximately \$242,000 for the nine months ended September 30, 2011 on the purchase of equipment. We spent \$17,000 on principal payments to repay a capital lease. Proceeds from a loan payable provided \$118,000. We generated approximately \$10,000 from issuance of Common Stock.

At September 30, 2011, we had cash of approximately \$3,687,000 and we expect the cash to fund our operations through March 31, 2012. We will need to raise substantial additional capital to complete our clinical trials, obtain marketing approvals and commercialize our products.

**Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements, including unrecorded derivative instruments 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. We have certain warrants and options outstanding but we do not expect to receive sufficient proceeds from the exercise of these instruments unless and until the trading price of our Common Stock is significantly greater than the applicable exercise prices of the options and warrants.

**Effect of Inflation and Changes in Prices**

Management does not believe that inflation and changes in price will have a material effect on our operations.

---

**Table of Contents**

**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, and are continuing the existing business operations of InVivo as a wholly-owned subsidiary.

**Overview**

InVivo was incorporated on November 28, 2005. InVivo was founded to develop and commercialize new technologies for the treatment of spinal cord injuries. InVivo's proprietary technology was co-invented by Robert S. Langer, ScD, Professor at Massachusetts Institute of Technology 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 CMCC and MIT.

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, 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. The Company expects 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.

## **Table of Contents**

The Company will be required to demonstrate safety and efficacy in human clinical studies before it can submit a PMA to the FDA. The Company plans 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 the Company 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 the Company is unable to raise additional capital to continue to fund the Company. Please see **Risk Factors** beginning on page 5 for a more detailed discussion of these risks.

If the product is approved by the FDA, the Company will need to expand manufacturing capacity, and establish sales, marketing and distribution channels to sell the product. The Company intends 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. By 2011, based on the Company's estimates, the total addressable market for acute spinal cord injury will be 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, 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 2011.*



**Table of Contents**

These costs place a tremendous financial burden on families, insurance providers, and government agencies. Moreover, despite all financial investment, the patient remains disabled for life since current medical interventions address only the symptoms of spinal cord injury rather than the underlying neurological cause.

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

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

## **Table of Contents**

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 ( 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

## **Table of Contents**

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.

### **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  $\mu$ M AND 50  $\mu$ M, 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  $\mu$ M). (e) SCHEMATIC OF SURGICAL INSERTION OF THE IMPLANT INTO THE SPINAL CORD.**



## **Table of Contents**

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

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

### **Pilot Primate Study 2008**

We believe the non-human primate model is the best surrogate for potentially how spinal cord injury products will work in humans. To date, the PLGA-polylysine scaffolding device has been evaluated in two primate studies. The first study involving four primates, was completed in 2008, was published in the Journal of Neuroscience Methods, and focused mainly on neuromotor assessment criteria following the model spinal cord injury. The second primate study which involved sixteen primates also included collecting quantitative electromyographic and kinematic analyses.

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

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

### **FIGURE 4. DEVICE INSERTED INTO HEMI-SECTION**

**Table of Contents**

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

**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).

**2<sup>nd</sup> 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.

## **Table of Contents**

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

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

### **FIGURE 7. IPSILATERAL HINDLIMB TREADMILL HANDCAM NEUROMOTOR SCORE**

#### **3<sup>rd</sup> 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 trial 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.

## **Table of Contents**

### **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 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.

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 at 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



## **Table of Contents**

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 10 issued US patents and 3 pending US patents as well as 67 international patents and 34 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.

## **Table of Contents**

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. We believe that we have sufficient capital resources to make all of such payments. 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.

## **Description of Properties**

Our executive offices are located in leased premises at One Broadway, 14<sup>th</sup> 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.

## **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.

**Table of Contents****SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following tables set forth certain information regarding the beneficial ownership of our Common Stock as of December 9, 2011 by (i) each person who, to our knowledge, owns more than 5% of our Common Stock; (ii) each of the directors and executive officers of the Company; and (iii) all of our executive officers and directors as a group. Unless otherwise indicated in the footnotes to the following tables, each person named in the table has sole voting and investment power and that person's address is c/o InVivo Therapeutics Holdings Corp., One Broadway, Cambridge, Massachusetts 02142. Shares of Common Stock subject to options or warrants currently exercisable or exercisable within 60 days of December 9, 2011 are deemed outstanding for computing the share ownership and percentage of the person holding such options and warrants, but are not deemed outstanding for computing the percentage of any other person.

|  |            |       |
|--|------------|-------|
| Frank Reynolds(1)(2)   | 15,540,122 | 29.3% |
| Robert S. Langer   | 8,262,360  | 15.7% |
| Kevin Kimberlin(3)   | 7,066,721  | 12.2% |
| Adam K. Stern(1)(4)  | 2,499,456  | 4.7%  |
| Richard J. Roberts(1)(5)                                       | 894,897    | 1.7%  |
| George Nolen(1)(6)   | 140,302    | *     |
| Christi Pedra(1)(7)  | 171,285    | *     |
| Edward Wirth(1)(8)   |            |       |
| All directors and executive officers as a group (6 persons)(1) | 19,246,062 | 35.2% |

\* Less than one percent

(1) Officer and/or director.

(2) Represents (i) 15,147,660 shares of Common Stock and (ii) 392,462 shares issuable upon the exercise of stock options.

(3) Represents (i) 1,947,321 shares owned by Optical Partners, LLC and (ii) 5,119,400 shares underlying warrants held by Spencer Trask that it received in connection with the bridge financing and the 2010 Private Placement.

(4) Represents (i) 500,083 shares owned by Adam Stern; (ii) 40,000 shares underlying warrants owned by Adam Stern; (iii) 58,334 shares issuable upon the exercise of stock options held by Adam Stern; (iv) 801,507 shares owned by ST Neuroscience Partners, LLC; (v) 301,400 shares underlying warrants owned by ST Neuroscience Partners, LLC; (vi) 475,079 shares owned by Pavilion Capital Partners, LLC; and (vii) 323,053 shares owned by Piper Venture Partners, LLC.

(5) Represents shares issuable upon the exercise of stock options.

(6) Represents (i) 10,000 shares underlying Investor Warrants, (ii) 10,000 shares of Common Stock and (iii) 120,302 shares issuable upon the exercise of stock options.

(7) Represents (i) 151,285 shares issuable upon the exercise of stock options, (ii) 10,000 shares underlying Investor Warrants and (iii) 10,000 shares of Common Stock.

(8) Edward Wirth joined the Company as Chief Science Officer on December 5, 2011.



**Table of Contents****DIRECTORS AND EXECUTIVE OFFICERS**

The following persons are the executive officers and directors of the Company and hold the positions set forth opposite their name.

| <b>Name</b>         | <b>Age</b> | <b>Position</b>  |
|---------------------|------------|--|
| Frank M. Reynolds   | 49         | Chairman of the Board of Directors, Chief Executive Officer,<br>Chief Financial Officer* |
| Edward D. Wirth III | 47         | Chief Science Officer  |
| Richard J. Roberts  | 67         | Director, Scientific Advisory Board Member   |
| George Nolen        | 55         | Director (Lead Director)   |
| Christi M. Pedra    | 53         | Director   |
| Adam K. Stern       | 46         | Director   |

\* Mr. Reynolds will serve as Chief Financial Officer pending the Company's hiring of an individual to serve in such capacity. The Company has initiated a search to locate such a qualified individual.

Spencer Trask was granted the right to designate one member to our Board of Directors for a period of two years following the 2010 Private Placement and has designated Adam K. Stern to fill such Board seat.

There are no family relationships between any director, executive officer or person nominated or chosen by the Company to become a director or executive officer of the Company.

**Officers**

**Frank M. Reynolds, Chairman of the Board of Directors, Chief Executive Officer and Chief Financial Officer**, has been CEO, Chairman and CFO of the Company since October 2010 and has been CEO of InVivo since 2005. He is an Executive Board Member of the Irish American Business Chamber and has served on the board of the Special Olympics of Massachusetts, Philadelphia Cares, and Wharton Consulting Partners. Mr. Reynolds brings to the Board over 25 years of executive management experience. He is the former Director of Global Business Development at Siemens Corporation where he was responsible for new business in 132 countries. He was the founder & CEO of Expand the Knowledge, Inc., an IT consulting company with a focus on life sciences. In addition, Mr. Reynolds' executive role at InVivo provides him a deep knowledge of the business of the Company.

Mr. Reynolds suffered an injury to his spine in 1992. While recovering from this injury, he took the opportunity to earn two Master's degrees and he currently holds a Master of Business Administration from Sloan Fellows Program in Global Innovation and Leadership 2006, Massachusetts Institute of Technology; a Master's of Science in Technology Management 2005, The Wharton School of Business, University of Pennsylvania; a Master's of Science in Engineering 2003, University of Pennsylvania; a Master's of Science in Management Information Systems 2001, Temple University; a Master's of Science in Health Administration 1996; Saint Joseph's University; and a Master's of Science in Psychology 1994, Chestnut Hill College. He also has a Bachelor of Science in Marketing 1984, Rider University.

**Dr. Edward D. Wirth III, Chief Science Officer**, joined the Company in December 2011. Prior to joining the Company, Dr. Wirth was the Medical Director, Regenerative Medicine at Geron Corporation which he joined in August 2004 and where he has led the effort to initiate clinical trials of Geron Corporation's human embryonic stem cell-derived products. From January 2002 to May 2004, Dr. Wirth held academic appointments at Rush-Presbyterian St. Luke's Medical Center and at the University of Chicago. From July 1997 to December 2001, Dr. Wirth led the University of Florida team that performed the first human embryonic spinal cord transplant in the United States. This pilot study demonstrated the feasibility and safety of implanting embryonic spinal cord cells into patients with post-traumatic syringomyelia.

## Table of Contents

### Directors

**Dr. Richard J. Roberts, PhD, Director**, has been a director of the Company since October 2010 and a director of InVivo since November 2008. Dr. Roberts has been the Chief Scientific Officer at New England Biolabs since July 1, 2005. Dr. Roberts joined InVivo's Scientific Advisory Board in June 2007. He was awarded the 1993 Nobel Prize in Physiology or Medicine along with Phillip Allen Sharp for the discovery of introns in eukaryotic DNA and the mechanism of gene-splicing. He holds a B.Sc. in Chemistry and a Ph.D. in Organic Chemistry from the University of Sheffield, U.K. Dr. Roberts has discovered and cloned restriction enzymes and been involved in studies of Adenovirus-2, beginning with studies of transcription that led to the discovery of split genes and mRNA splicing. His laboratory has pioneered the application and development of computer methods for protein and nucleic acid sequence analysis that continues to be a major research focus for Dr. Roberts. Dr. Roberts brings to the Board an understanding of the science and technology involved in the Company's business.

**George Nolen, Lead Director**, has been a director of the Company since October 2010 and a director of InVivo since December 2009. Mr. Nolen was the President and Chief Executive Officer of Siemens Corporation, the U.S. subsidiary of Siemens, AG, from 2004 until his retirement in August of 2009. Prior to his role as Siemens USA's CEO, Mr. Nolen held numerous roles in Siemens including President of Siemens' Information and Communications division, overseeing this business from 1998 to 2004. He is a 1978 graduate of Virginia Tech, where he currently serves as the Rector of the University's Board of Visitors. Mr. Nolen brings to the Board extensive leadership and business experience through his successful and long-running career at Siemens.

**Christi M. Pedra, Director**, has been a director of the Company since October 2010 and a director of InVivo since November 2008. Ms. Pedra became the Senior Vice President, Strategic New Business Development & Marketing Siemens Healthcare of Siemens Medical USA in January 2010. Previously she served as Chief Executive Officer of Siemens Hearing Instruments, Inc. from January 2007 through December 2009. She was charged with leading the company's sales, manufacturing, product development, customer relations and research and development in the United States. From October 2003 through December 2006, she served as Vice President and Chief Operating Officer of Siemens One. Prior to her role with Siemens One, Ms. Pedra served as Vice President of Executive Relations for Siemens Corporation in the Office of the President. Currently, Ms. Pedra is a member of the National Collegiate Athletic Association Leadership Advisory Board. She also serves on the National Council for Liberal Education America's Promise and takes part in several formal and informal mentoring programs. And in 2002, Ms. Pedra was nominated and selected to be a David Rockefeller Fellow, a one-year leadership program sponsored by the NYC Partnership and the David Rockefeller Foundation. Ms. Pedra received her MBA from Rutgers University. Ms. Pedra brings to the Board extensive management experience through her many roles at Siemens.

**Adam K. Stern, Director**, has been a director of the Company since October 2010 and was designated as such by Spencer Trask. Mr. Stern is Senior Managing Director of Spencer Trask, and has over 20 years of venture capital and investment banking experience focusing primarily on the technology and life science sectors of the capital markets. He currently manages the structured finance group of Spencer Trask. Mr. Stern joined Spencer Trask in September 1997 from Josephthal & Co., members of the New York Stock Exchange, where he served as Senior Vice President and Managing Director of Private Equity Marketing and held increasingly responsible positions from 1989 to 1997. He has been a licensed securities broker since 1987 and a General Securities Principal since 1991. Mr. Stern currently sits on the boards of various private companies. Mr. Stern holds a Bachelor of Arts degree with honors from The University of South Florida in Tampa. Mr. Stern brings to the Board extensive financial experience through his career in the financial sector.

**Table of Contents**

**NON-EXECUTIVE OFFICER AND SCIENTIFIC AND BUSINESS ADVISORY BOARDS**

In addition to our executive officers and directors, our team includes a non-executive officer and both a Scientific Advisory Board and a Business Advisory Board that provide guidance to the Company. The Scientific Advisory Board reviews the progress of the Company's product development and provides input to the Company's management regarding scientific issues relating to the Company's product and potential markets. The Business Advisory Board provides business expertise and regulatory advice to the CEO and the Company. Both boards are advisory only and do not have the power to make decisions on behalf of the Company. The following persons are the non-executive officer and members of our advisory boards and hold the positions set forth opposite their name.

|                        |   |
|------------------------|---|
| Dr. Eric J. Woodard    | Chief Medical Officer, Scientific Advisory Board Member |
| Dr. Richard J. Roberts | Director, Scientific Advisory Board Member              |
| Dr. Robert S. Langer   | Scientific Advisory Board Member                        |
| V. Reggie Edgerton     | Scientific Advisory Board Member                        |
| Jonathan R. Slotkin    | Scientific Advisory Board Member                        |
| Todd Albert            | Scientific Advisory Board Member                        |
| Paul Mraz              | Business Advisory Board Member                          |
| David Feigal           | Business Advisory Board Member                          |

**Eric J. Woodard, M.D., Chief Medical Officer**, is the Chief, Neurosurgery at New England Baptist Hospital in Boston. Dr. Woodard was appointed to InVivo's Scientific Advisory Board in June 2007 and became Chief Medical Officer of InVivo in September 2008. Dr. Woodard received his medical degree from Pennsylvania State University and completed his residency in Neurological surgery at Emory University. Following residency, Dr. Woodard completed a fellowship in complex spinal surgery at the Medical College of Wisconsin under Dr. Sanford Larsen. He is a diplomat of the American Board of Neurological Surgeons.

Dr. Woodard was formerly Chief of the Division of Spinal Surgery in the Department of Neurological Surgery at Brigham and Women's Hospital, where he held the rank of Assistant Professor in Surgery at Harvard Medical School. He has been an editorial board member for The Journal of Spinal Disorders, Spine Universe.com and is an ad hoc reviewer for Neurosurgery, Journal of Neurosurgery and the New England Journal of Medicine. He is the immediate past chairman of the AO Spine North America Board and serves on the Board of AO Spine International.

**Robert S. Langer, ScD**, Scientific Advisory Board Member, is the David H. Koch Institute Professor at the Massachusetts Institute of Technology (MIT). Dr. Langer has written over 1,100 articles. He also has approximately 760 issued and pending patents worldwide. Dr. Langer's patents have been licensed or sublicensed to over 220 pharmaceutical, chemical, biotechnology and medical device companies. He received his Bachelor's Degree from Cornell University in 1970 and his Sc.D. from the Massachusetts Institute of Technology in 1974, both in Chemical Engineering.

He served as a member of the United States Food and Drug Administration's SCIENCE Board from 1995-2002 and as its Chairman from 1999-2002. Dr. Langer has received over 180 major awards including the 2006 United States National Medal of Science; the Charles Stark Draper Prize and the 2008 Millennium Prize. In 1989, Dr. Langer was elected to the Institute of Medicine of the National Academy of Sciences, and in 1992 he was elected to both the National Academy of Engineering and to the National Academy of Sciences. Dr. Langer has received honorary doctorates from 16 national and international universities.

**Dr. Reggie Edgerton, PhD**, Scientific Advisory Board Member, has been the Director of U.C.L.A.'s Edgerton Lab since 1968 and is a professor in the Department of Physiological Sciences at U.C.L.A. His research is focused on neural control of movement and how this neural control adapts to altered use and after spinal cord injury. He completed his Ph.D. under the direction of Drs. Wayne Van Huss, Rex Carrow, and William Heusner at Michigan State University.

## **Table of Contents**

Dr. Edgerton is on the Scientific Advisory Board of The Christopher Reeves Foundation (CRF) and his laboratory is one of eight in the world receiving funding from the CRF. In addition to serving on the board of the CRF, he is currently on the Scientific Advising board of the American Paralysis Association. Dr. Edgerton has co-authored two books and is the author of approximately 300 research papers.

**Jonathan Slotkin, MD**, Scientific Advisory Board Member, is a clinical neurosurgeon and research scientist. Clinically, Dr. Slotkin has expertise in complex spinal surgery, minimally invasive spinal surgery, spinal oncology surgery and brain tumor surgery. Dr. Slotkin completed residency training in neurosurgery at Harvard Medical School, Brigham and Women's Hospital. He performed a fellowship in complex spinal surgery with Dr. Eric J. Woodard. He is the co-editor of a two-volume publication on spinal surgery. Dr. Slotkin is currently a neurosurgeon with the Washington Brain and Spine Institute.

Dr. Slotkin has authored or co-authored several peer-reviewed scientific publications in the areas of repair after spinal cord injury in animal models, and in vivo quantum dot labeling of neural stem cells.

**Todd J. Albert, MD**, Scientific Advisory Board Member, is the James Edwards Professor and Chair of the Department of Orthopaedics at Jefferson Medical College. He is also the President of the Rothman Institute in Philadelphia. Previously, he served as Co-director of Reconstructive Spine Surgery and the Spine Fellowship Program at Thomas Jefferson University. Dr. Albert graduated magna cum laude from Amherst College and received his doctor of medicine degree from the University of Virginia School of Medicine.

Dr. Albert serves on the boards of several scientific journals, including Spine, The Spine Journal, and The Journal of Spinal Disorders and Techniques, as well as medical associations. He is Chair of Network Development for the National Spine Network. Dr. Albert has published over 200 scientific articles, authored over 40 book chapters, and seven textbooks on spinal surgery.

**Paul Mraz**, Business Advisory Board, currently serves as Chief Executive Officer of CeraPedics, Inc., a medical device company. Mraz most recently served as Chairman and CEO of Angstrom Medica, Inc. (acquired by Pioneer Surgical Technology). Prior to Angstrom Medica, Mraz was a Principal of Link Spine Group Inc. as Vice President - Worldwide Marketing and International Sales until its acquisition by Johnson & Johnson in June 2003.

Mr. Mraz currently serves as a Director of superDimension, Ltd. (Herzliya, ISRAEL and Plymouth, MN). Mraz received a B.S. degree in Mechanical Engineering from Lafayette College and an M.S. degree in Mechanical Engineering and Biomechanics from Case Western Reserve University. He holds six US Patents for various medical devices and is an active advisor to numerous venture capital groups.

**David W. Feigal Jr., MD**, Business Advisory Board, recently served as Vice President, Global Regulatory at Amgen, Inc. Previously, Dr. Feigal was Senior Vice President, Head of Global Regulatory and Global Safety Surveillance at Elan. Prior to joining Elan in November 2006, he spent 12 years with the FDA. During his time at the FDA, he was Head of the Center for Devices and Head of the Center for Biologics for five years each.

Before joining the FDA, Dr. Feigal worked for 10 years within the academic and hospital settings of the University of California in San Diego, San Francisco and Davis. He holds a BA from University of Minnesota, an MD from Stanford University and a Master of Public Health from the University of California, Berkeley.

The Company does not pay Members of its Advisory Boards any cash compensation and plans to compensate the Scientific Advisory and Business Advisory Boards through the issuance of stock options.

**Table of Contents****EXECUTIVE COMPENSATION****Compensation of ITHC Executive Officers and Directors****Summary Compensation**

For the three most recently completed fiscal years, no compensation was paid to any executive officer of ITHC.

**Outstanding Equity Awards at Fiscal Year End**

None of the ITHC executive officers held any options or other equity awards at March 31, 2010.

**Director Compensation**

None of the ITHC directors received any compensation for service as a director of ITHC during the fiscal year ended March 31, 2010.

**Compensation of InVivo Executive Officers and Directors****Summary Compensation Table**

In connection with the consummation of the Merger, InVivo's Chief Executive Officer, Frank M. Reynolds, became the Chief Executive Officer of the Company. The following summary compensation table sets forth the compensation paid for services rendered to InVivo during the past two fiscal years by its Chief Executive Officer. There were no other executive officers during the past two fiscal years. All information relating to option awards reflects the exchange of InVivo options for ITHC options in the Merger.

**Summary Compensation Table**

| Name and Principal Position | Fiscal Year | Salary     | Bonus      | Option Awards(1)(2) | All Other Compensation | Total      |
|-----------------------------|-------------|------------|------------|---------------------|------------------------|------------|
| Frank Reynolds              | 2010        | \$ 375,000 | \$ 150,000 |                     |                        | \$ 525,000 |
| Chief Executive Officer     | 2009        | \$ 275,000 | \$ 40,000  | \$ 350,418          |                        | \$ 665,418 |

- (1) The amounts shown in this column represent the aggregate grant date fair value of awards computed in accordance with Financial Accounting Standards Board ( FASB ) Accounting Standards Codification ( ASC ) Topic 718, not the actual amounts paid to or realized by the Chief Executive Officer during fiscal 2010 and fiscal 2009. FASB ASC Topic 718 fair value amount as of the grant date for stock options generally is spread over the number of months of service required for the grant to vest.
- (2) The fair value of each stock option award is estimated as of the date of grant using the Black-Scholes valuation model. Additional information regarding the assumptions used to estimate the fair value of all stock options awards can be found in the section entitled Stock-Based Compensation in Management's Discussion and Analysis of Financial Condition and Results of Operations.

**Agreements with Officers and Directors**

In November 2006, InVivo entered into an Agreement with each of: (i) Frank Reynolds, InVivo's current Chief Executive Officer; (ii) Robert Langer, InVivo's current Scientific Advisory Member; and (iii) Yang D. Teng. The Agreement provided for the repurchase of a party's unvested shares of common stock by the other parties upon the occurrence of certain events. As of the date of this prospectus, all shares granted to each of the parties have vested.

The Company entered into an amended and restated executive employment agreement (the Employment Agreement) with Mr. Reynolds on March 15, 2011. The Employment Agreement, among other things, established Mr. Reynolds' compensation as follows: (i) annual base salary of \$477,000; (ii) up to \$3,200 per



**Table of Contents**

month for living expenses for the time period of January 2011 through December 2012; (iii) annual compensation for other fringe benefits approved in the amount of \$19,900 per year; and (iv) an annual bonus, with a 2011 target of \$238,500. Mr. Reynolds' bonus payment is subject to the achievement of certain corporate objectives for fiscal year 2011, each of which will entitle him to a corresponding percentage of the target.

Under the Employment Agreement, if Mr. Reynolds' employment is terminated by the Company without cause, or by Mr. Reynolds as a result of a constructive termination by the Company, or as a result of Mr. Reynolds' death or disability, then the Company is obligated to pay severance (consisting of base salary in effect at the time of termination) to Mr. Reynolds (or Mr. Reynolds' legal representatives) for a period of 18 months. In addition, if Mr. Reynolds' employment is terminated by the Company without cause, or by Mr. Reynolds as a result of a constructive termination by the Company, the Company will be obligated to pay Mr. Reynolds his target bonus, prorated based on the number of days of such fiscal year that have elapsed as of the termination date, as well as up to 18 months of health insurance benefits. Severance payments are contingent on execution of a general waiver and release of claims against the Company and certain of its affiliates, and are in addition to accrued obligations to Mr. Reynolds unpaid by the Company prior to the time of termination, death or disability. The Employment Agreement also contains various restrictive covenants, including covenants relating to non-competition, non-solicitation, confidentiality and cooperation.

Mr. Reynolds was also granted a nonqualified stock option to purchase 250,000 shares of Common Stock under the 2010 Plan at an exercise price of \$1.20, which is equal to the closing price of the Common Stock on the date of execution of the Employment Agreement and the date the stock option was granted (the "Date of Grant"). This stock option shall vest and become exercisable as to 25% of the shares subject to the option on each of the first four anniversaries of the Date of Grant, provided that Mr. Reynolds remains an employee, consultant or director of the Company on each vesting date.

The Company and Dr. Wirth executed an employment offer letter on September 24, 2011 (the "Offer Letter"), which provides for the employment of Dr. Wirth at an annual salary of \$277,000. Dr. Wirth will also be eligible for an annual bonus, with a target bonus equal to 20% of his annual salary, after one year of employment. Upon commencement of employment, Dr. Wirth was granted an option to purchase 775,000 shares of Common Stock at an exercise price of \$1.87 (the closing price on the date of grant). Such option will vest as to 25% of the shares subject to the option on each of the first, second, third and fourth anniversaries of the date of grant, provided that Dr. Wirth remains employed by the Company on each vesting date. In addition, Dr. Wirth will receive a \$37,000 sign on bonus payable after 30 days of employment.

**Outstanding Equity Awards at 2010 Fiscal Year-End**

The following table summarizes the equity awards made to our named executive officers that were outstanding at December 31, 2010.

| Name              | No. of Securities Underlying Unexercised Options (#) Exercisable | No. of Securities Underlying Unexercised Options (#) Unexercisable | Option Exercise Price | Option Expiration Date |
|-------------------|--|--|-----------------------|------------------------|
| Frank Reynolds(1) | 196,231  | 588,693  | \$ 0.91               | 12/12/2019             |

- (1) The options were granted on December 12, 2009. 196,231 shares vested on each of December 12, 2010 and December 12, 2011. An additional 196,231 shares will vest on each of the third and fourth anniversaries of the date of grant.

**Board of Directors and Corporate Governance**

Our Board of Directors consists of five (5) members. On the Closing of the Merger, Peter L. Coker and Peter A. Reichard, the sole members of the Board of Directors of ITHC, resigned, and simultaneously therewith, a new

**Table of Contents**

Board of Directors was appointed. The Board consists of four (4) members who were former directors of InVivo and Adam K. Stern, who was appointed at the closing of the Merger at the request of Spencer Trask.

**Board Independence**

The Company is not currently listed on any national securities exchange or in an inter-dealer quotation system that has a requirement that the Board of Directors be independent. However, in evaluating the independence of its members and the composition of the committees of the Board of Directors, the Board utilizes the definition of "independence" as that term is defined by the listing standards of the Nasdaq Stock Market and the applicable SEC rules, including the rules relating to the independence standards of an audit committee and the non-employee director definition of Rule 16b-3 promulgated under the Exchange Act. Using these standards, the Board of Directors determined that Messrs. Nolen and Roberts and Ms. Pedra are currently "independent" directors. The Board determined that Mr. Stern is not independent as a result of the payments to Spencer Trask and that Mr. Reynolds is not independent as a result of his employment relationship with the Company.

**Committees of the Board**

The Board has designated two principal standing committees, the Audit Committee and the Governance, Nominating and Compensation Committee (the "GNC Committee"). The current members of the Audit Committee and the GNC Committee are identified in the following table:

| Name          | Audit Committee | GNC Committee |
|---------------|-----------------|---------------|
| George Nolen  | Chair           | X             |
| Christi Pedra | X               | Chair         |
| Rich Roberts  | X               | X             |

*Audit Committee*

The Board has a standing Audit Committee established in accordance with Section 3(a)(58)A of the Exchange Act. The Audit Committee assists the Board in fulfilling its responsibilities to stockholders concerning the Company's financial reporting and internal controls. The Audit Committee facilitates open communication among the Audit Committee, the Board, the Company's independent registered public accounting firm and management. The Audit Committee discusses with management and the Company's independent registered public accounting firm the financial information developed by the Company, the Company's systems of internal controls and the Company's audit process. The Audit Committee is solely and directly responsible for appointing, evaluating, retaining, and, where necessary, terminating the engagement of the Company's independent registered public accounting firm. The independent registered public accounting firm meets with the Audit Committee (both with and without the presence of the Company's management) to review and discuss various matters pertaining to the audit, including the Company's financial statements, the report of the independent registered public accounting firm on the results, scope and terms of their work, and their recommendations concerning the financial practices, controls, procedures and policies employed by the Company.

The Audit Committee pre-approves all audit services to be provided to the Company by the principal auditor and all other services (including reviewing, attestation and non-audit services) to be provided to the Company by the independent registered public accounting firm.

The Audit Committee is charged with establishing procedures for (i) the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters; and (ii) the confidential, anonymous submission by employees of the Company of concerns regarding questionable accounting or auditing matters. The Audit Committee reviews and oversees all related party transactions on an ongoing basis. The Audit Committee is authorized, without further action by the Board, to engage independent



## **Table of Contents**

legal, accounting and other advisors as it deems necessary or appropriate to carry out its responsibilities. The Board has adopted a written charter for the Audit Committee, a copy of which is available on the Company's website.

The Board has determined that all of the members of the Audit Committee are independent (as defined by the listing standards of the Nasdaq Stock Market and the applicable SEC rules), and that the Audit Committee members meet the independence requirements contemplated by Rule 10A-3 under the Exchange Act. The Board has determined that George Nolen is an audit committee financial expert (as defined in Item 407(d)(5) of Regulation S-K).

### *GNC Committee*

The GNC Committee assists the Board in fulfilling its responsibilities relating to (i) compensation of the Company's executive officers, (ii) the director nomination process and (iii) reviewing the Company's compliance with SEC corporate governance requirements. The Board has adopted a written charter for the GNC Committee, a copy of which is available on the Company's website. The Board has determined that all of the members of the GNC Committee are independent (as defined by the listing standards of the Nasdaq Stock Market and the applicable SEC rules).

The GNC Committee determines salaries, incentives and other forms of compensation for the Chief Executive Officer and the executive officers of the Company and reviews and makes recommendations to the Board with respect to director compensation. The GNC Committee annually reviews and approves the corporate goals and objectives relevant to the compensation of the Chief Executive Officer, evaluates the Chief Executive Officer's performance in light of these goals and objectives, and sets the Chief Executive Officer's compensation level based on this evaluation. The GNC Committee meets without the presence of executive officers when approving or deliberating on executive officer compensation, but may invite the Chief Executive Officer to be present during the approval of, or deliberations with respect to, other executive officer compensation. The GNC Committee reviews and approves the terms of any and all offer letters, employment agreements, severance agreements, change-in-control agreements, indemnification agreements and other material agreements between the Company and its executive officers. In addition, the GNC Committee administers the Company's stock incentive compensation and equity-based plans.

The GNC Committee makes recommendations to the Board concerning all facets of the director nominee selection process. Generally, the GNC Committee identifies candidates for director nominees in consultation with management and the independent members of the Board, through the use of search firms or other advisers, through the recommendations submitted by stockholders or through such other methods as the GNC Committee deems to be helpful to identify candidates. Once candidates have been identified, the GNC Committee confirms that the candidates meet the independence requirements and qualifications for director nominees established by the Board. The GNC Committee may gather information about the candidates through interviews, questionnaires, background checks, or any other means that the GNC Committee deems to be helpful in the evaluation process. The GNC Committee meets to discuss and evaluate the qualities and skills of each candidate, both on an individual basis and taking into account the overall composition and needs of the Board. Upon selection of a qualified candidate, the GNC Committee would recommend the candidate for consideration by the full Board.

In considering whether to include any particular candidate in the Board's slate of recommended director nominees, the Board will consider the candidate's integrity, education, business acumen, knowledge of the Company's business and industry, experience, diligence, conflicts of interest and the ability to act in the interests of all stockholders. As a matter of practice, the Board considers the diversity of the backgrounds and experience of prospective directors as well as their personal characteristics (e.g., gender, ethnicity, age) in evaluating, and making decisions regarding, Board composition, in order to facilitate Board deliberations that reflect a broad range of perspectives. The Board does not assign specific weights to particular criteria and no particular criterion

## **Table of Contents**

is a prerequisite for each prospective nominee. The Company believes that the backgrounds and qualifications of its directors, considered as a group, should provide a composite mix of experience, knowledge and abilities that will allow the Board to fulfill its responsibilities.

The GNC Committee will consider director candidates who are recommended by the stockholders of the Company. Such recommendation for nomination must be in writing and include the following:

the name and address of the stockholder making the recommendation;

the number of shares of Common Stock that such stockholder owns beneficially and holds of record;

the name and address of the individual recommended for consideration as a director nominee;

the principal occupation and experience of the director nominee;

the total number of shares of Common Stock that the stockholder making the recommendation will vote for the director nominee;

a written statement from the stockholder making the recommendation stating whether the director nominee has indicated his or her willingness to serve if elected and why such recommended candidate would be able to fulfill the duties of a director; and

any other information regarding the director nominee that is required to be included in a proxy statement filed pursuant to the rules of the SEC.

Nominations must be sent to the GNC Committee by U.S. mail, courier or expedited delivery service to InVivo Therapeutics Holdings Corp., One Broadway, 14<sup>th</sup> Floor, Cambridge, Massachusetts 02142, Attn: Chair, GNC Committee. The chair of the GNC Committee will then provide the nomination to the GNC Committee for consideration. Assuming that the required material has been provided on a timely basis, the GNC Committee will evaluate stockholder-recommended candidates by following substantially the same process, and applying substantially the same criteria, as it follows for candidates submitted by others.

## **Stockholder Communications with the Board**

Stockholders may communicate with the Board by sending written communications to the Board or any individual member of the Board to the following address: Board, c/o Secretary, InVivo Therapeutics Holdings Corp., One Broadway, 14<sup>th</sup> Floor, Cambridge, Massachusetts 02142. The Secretary will forward all such correspondence accordingly, except for mass mailings, job inquiries, surveys, business solicitations or advertisements, personal grievances, matters as to which the Company tends to receive repetitive or duplicative communications, or patently offensive or otherwise inappropriate material.

## **Board Leadership Structure**

The Board does not have a policy on whether the offices of Chairman and Chief Executive Officer should be separate and, if they are to be separate, whether the Chairman should be selected from among the independent directors or should be an employee of the Company. In the event the Chairman is not an independent director, the Board may designate a lead independent director. The duties of the lead independent director, as set forth in the Company's Corporate Governance Guidelines, include (i) chairing any meeting of the independent directors in executive session, (ii) facilitating communications between other members of the Board and the Chairman (however, each director is free to communicate directly with the Chairman), (iii) in the event a stockholder seeks to communicate with the Board, accepting and responding to such communications in conjunction with the Chairman, and (iv) working with the Chairman (a) in the preparation of the agenda for each Board meeting, (b) in scheduling the time devoted to matters at each Board meeting and (c) as required, in determining the need for special meetings of the Board. The appointment of lead independent director rotates among the independent directors, but no more frequently than annually, and the

Board periodically reviews the matter to determine if and when a rotation is advisable. The lead independent director is currently George Nolen.

**Table of Contents****Director Compensation for Fiscal 2010**

The following table sets forth compensation earned and paid to each non-employee director of InVivo for service as a director during 2010.

| Name                  | Fees Earned or<br>Paid in Cash<br>(\$) | Option<br>Awards<br>\$(1) | Total<br>(\$) |
|-----------------------|--|---------------------------|---------------|
| George Nolen(2)       | \$ 2,000                               | \$ 71,520                 | \$ 73,520     |
| Christi M. Pedra(3)   | \$ 2,000                               | \$ 71,520                 | \$ 73,520     |
| Richard J. Roberts(4) | \$ 2,000                               | \$ 71,520                 | \$ 73,520     |
| Adam K. Stern(5)      | \$ 1,000                               | \$ 71,520                 | \$ 72,520     |

- (1) The amounts shown in the Option Awards column represent the aggregate grant date fair value of awards computed in accordance with ASC 718, not the actual amounts paid to or realized by the directors during fiscal 2010.
- (2) As of December 31, 2010, Mr. Nolen held options (vested and unvested) to purchase an aggregate of 173,934 shares of our Common Stock.
- (3) As of December 31, 2010, Ms. Pedra held options (vested and unvested) to purchase an aggregate of 173,934 shares of our Common Stock.
- (4) As of December 31, 2010, Mr. Roberts held options (vested and unvested) to purchase an aggregate of 917,547 shares of our Common Stock.
- (5) As of December 31, 2010, Mr. Stern held options (vested and unvested) to purchase an aggregate of 50,000 shares of our Common Stock. On December 10, 2010, based upon the recommendation of the GNC Committee, the Board adopted a compensation policy for non-employee directors. The policy provides that each non-employee director shall be paid an annual retainer of \$25,000 per year (paid quarterly and delivered at each regularly scheduled quarterly Board meeting). In addition, the policy provides that the Lead Independent Director, chairman of the GNC Committee and the chairman of the Audit Committee shall each receive an additional annual fee of \$5,000 (paid quarterly and delivered at each regularly scheduled quarterly Board meeting). Each non-employee director shall also receive \$1,000 for each in-person Board meeting attended, \$500 for each telephonic meeting of the Board attended, and \$500 for each committee meeting attended. Each non-employee director will also receive an annual grant, on December 10 of each calendar year, of a nonqualified stock option under the 2010 Plan to purchase up to 50,000 shares of the Company's Common Stock at an exercise price equal to the closing price of the Common Stock on the date of grant (the Director Option Date), and that such option shall be exercisable as to 1/12 of the original number of shares subject to the option on the one month anniversary of the Director Option Date and shall be exercisable as to an additional 1/12 of the original number of shares subject to the option each monthly anniversary thereafter until fully vested on the 12 month anniversary of the Director Option Date, provided that such director remains a director of the Company on each such vesting date. On December 10, 2010, the Company issued stock options for 50,000 shares exercisable at \$2.26 per share to each of George Nolen, Rich Roberts, Christi Pedra and Adam Stern. The aggregate fair value for the 200,000 shares granted was \$286,080.

**Code of Ethics**

We have adopted a code of business conduct and ethics that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer, controller and other senior financial officers. Our code of business conduct and ethics is posted under the Investor Relations Corporate Governance section of our website, [www.invivotherapeutics.com](http://www.invivotherapeutics.com). We intend to satisfy the disclosure requirement regarding any amendment to, or waiver of, a provision of the code of business conduct and ethics applicable to our principal executive officer, principal financial officer, controller or other senior financial officers by posting such information on our website.

## **Table of Contents**

### **InVivo s 2007 Stock Incentive Plan**

InVivo adopted a Stock Incentive Plan in 2007 (the 2007 Plan ). Pursuant to the 2007 Plan, InVivo s Board of Directors (or committees and/or executive officers delegated by the Board of Directors) had the authority to grant incentive and nonqualified stock options to InVivo s employees, officers, directors, consultants and advisors. Options granted under the 2007 Plan are exercisable for up to 10 years from the date of issuance. The Company assumed and adopted the 2007 Plan in the Merger, and granted option holders under the 2007 Plan new options to purchase Common Stock. No further options will be granted under the 2007 Plan.

### **2010 Equity Incentive Plan**

The Board of Directors adopted the 2010 Equity Incentive Plan on October 26, 2010. The Company s stockholders approved the 2010 Plan, as amended, on August 3, 2011. The 2010 Plan reserves a total of 3,500,000 shares of our Common Stock for issuance under the 2010 Plan. If an incentive award granted under the 2010 Plan expires, terminates, is unexercised or is forfeited, or if any shares are surrendered to us in connection with an incentive award, the shares subject to such award and the surrendered shares will become available for further awards under the 2010 Plan.

Shares issued under the 2010 Plan through the settlement, assumption or substitution of outstanding awards or obligations to grant future awards as a condition of acquiring another entity are not expected to reduce the maximum number of shares available under the 2010 Plan. In addition, the number of shares of Common Stock subject to the 2010 Plan, any number of shares subject to any numerical limit in the 2010 Plan, and the number of shares and terms of any incentive award are expected to be adjusted in the event of any change in our outstanding Common Stock by reason of any stock dividend, spin-off, split-up, stock split, reverse stock split, recapitalization, reclassification, merger, consolidation, liquidation, business combination or exchange of shares or similar transactions.

#### ***Administration***

The GNC Committee of the Board administers the 2010 Plan. Subject to the terms of the 2010 Plan, the GNC Committee has complete authority and discretion to determine the terms of awards under the 2010 Plan.

#### ***Grants***

The 2010 Plan authorizes the grant to 2010 Plan participants of nonqualified stock options, incentive stock options, restricted stock awards, restricted stock units, performance grants intended to comply with Section 162(m) of the Internal Revenue Code (as amended, the Code ) and stock appreciation rights, as described below:

Options granted under the 2010 Plan entitle the grantee, upon exercise, to purchase a specified number of shares from us at a specified exercise price per share. The exercise price for shares of Common Stock covered by an option cannot be less than the fair market value of the Common Stock on the date of grant unless agreed to otherwise at the time of the grant.

Restricted stock awards and restricted stock units may be awarded on terms and conditions established by the GNC Committee, which may include performance conditions for restricted stock awards and the lapse of restrictions on the achievement of one or more performance goals for restricted stock units.

The GNC Committee may make performance grants, each of which will contain performance goals for the award, including the performance criteria, the target and maximum amounts payable, and other terms and conditions.

**Table of Contents**

The 2010 Plan authorizes the granting of stock awards. The GNC Committee will establish the number of shares of Common Stock to be awarded and the terms applicable to each award, including performance restrictions.

Stock appreciation rights ( SARs ) entitle the participant to receive a distribution in an amount not to exceed the number of shares of Common Stock subject to the portion of the SAR exercised multiplied by the difference between the market price of a share of Common Stock on the date of exercise of the SAR and the market price of a share of Common Stock on the date of grant of the SAR.

***Duration, Amendment, and Termination***

The Board has the power to amend, suspend or terminate the 2010 Plan without stockholder approval or ratification at any time or from time to time. No change may be made that increases the total number of shares of Common Stock reserved for issuance pursuant to incentive awards or reduces the minimum exercise price for options or exchange of options for other incentive awards, unless such change is authorized by our stockholders within one year. Unless sooner terminated, the 2010 Plan terminates ten years after adoption.

**Table of Contents**

**CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

**Transactions with ITHC Shareholders**

***Split-Off and Share Cancellation***

On October 22, 2010, there were 6,999,981 shares of our Common Stock issued and outstanding before taking into account the issuance of shares of Common Stock to purchasers of units in the 2010 Private Placement and in the Merger and after giving pro forma effect to the Split-Off, as discussed below.

Upon the closing of the Merger, ITHC transferred all of its operating assets and liabilities to DSSC and split-off DSSC through the sale of all of the outstanding capital stock of DSSC. In connection with the Split-Off, 14,747,554 shares of Common Stock held by the Split-Off Shareholders were surrendered and cancelled without further consideration, other than the receipt of DSSC shares. An additional 1,014,490 shares of Common Stock were cancelled by a shareholder of ITHC for no consideration.

***Transactions with Spencer Trask and its Related Parties***

Spencer Trask also acted as finder to InVivo in connection with its sale of \$500,000 of principal amount of its bridge notes, which was consummated in September 2010. The Company issued investors participating in this bridge financing New Bridge Warrants to purchase an aggregate of 500,000 shares of the Company's Common Stock at a price of \$1.00 per share. The New Bridge Warrants have a term of five years and are fully exercisable. The bridge notes were converted into units in the 2010 Private Placement. Spencer Trask earned warrants (which are identical to the New Bridge Warrants) to purchase 100,000 shares of Common Stock of the Company at a price of \$1.00 per share as compensation for acting as a finder in the bridge financing. Affiliates of Spencer Trask purchased \$150,000 of bridge notes in the bridge financing.

In September 2010, several related parties to Spencer Trask purchased an aggregate of 3,895,643 shares of Common Stock from various shareholders of ITHC. The aggregate purchase price paid to such shareholders by the related parties for such shares was approximately \$49,000. Adam K. Stern, Senior Managing Director of Spencer Trask and its designee to serve on the Company's Board of Directors upon the closing of the 2010 Private Placement, along with certain entities in which Mr. Stern is the beneficial owner, owns 1,948,322 of these shares. In addition, Optical Partners, an entity beneficially owned by Kevin Kimberlin, the Chairman of Spencer Trask & Co., Inc., the parent corporation of Spencer Trask owns 1,947,321 of these shares.

ITHC engaged Spencer Trask as its exclusive placement agent in connection with the 2010 Private Placement. For its services, ITHC paid Spencer Trask (i) a cash fee equal to 10% of the gross proceeds raised in the 2010 Private Placement (\$1,300,000) and (ii) a non-accountable expense allowance equal to 3% of the gross proceeds raised in the 2010 Private Placement (\$390,000). In addition, the Company granted to Spencer Trask or its designees, for nominal consideration, five-year 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.

The Company has agreed to engage Spencer Trask as its warrant solicitation agent in the event the Company elects to call the Investor Warrants for redemption and in such case shall pay a warrant solicitation fee to Spencer Trask equal to five (5%) percent of the amount of funds solicited by Spencer Trask upon the exercise of the Investor Warrants following such redemption.

Spencer Trask was granted the right to designate one member to our Board of Directors for a period of two years following the closing of the 2010 Private Placement and has designated Adam K. Stern to fill such Board seat.

The Company has also agreed to pay Spencer Trask compensation of \$5,000 per month for a period of two years for services relating to strategies to maximize shareholder value; and entered into a non-exclusive finder's fee agreement with Spencer Trask providing that if Spencer Trask shall introduce us to a third party that

**Table of Contents**

consummates certain investment or business combination transactions with us during the eighteen (18) month period following the final closing of the 2010 Private Placement, Spencer Trask will be paid a finder's fee, payable in cash at the closing of such transaction, equal to 7% of the first \$1 million of consideration paid by or to the Company, plus 6% of the next \$1 million of consideration paid by or to the Company, plus 5% of the next \$5 million of the consideration paid by or to the Company, plus 4% of the next \$1 million paid by or to the Company, plus 3% of the next \$1 million paid by or to the Company, plus 2.5% of any consideration paid by or to the Company in excess of \$9 million. Spencer Trask will not be entitled to a finder's fee with respect to any transaction entered into with any party with whom the Company had a pre-existing relationship prior to the date of the specific introduction and who was not introduced to the Company by Spencer Trask.

Furthermore, we granted Spencer Trask a preferential right of first refusal to act as agent with respect to future private placements of the Company's securities for a period of eighteen (18) months from the date of the final closing of the 2010 Private Placement.

The Company agreed to indemnify Spencer Trask and other broker-dealers who are FINRA members selected by Spencer Trask to offer and sell units in the 2010 Private Placement, to the fullest extent permitted by law for a period of four (4) years from the closing of the 2010 Private Placement, against certain liabilities that may be incurred in connection with the 2010 Private Placement, including certain civil liabilities under the Securities Act, and, where such indemnification is not available, to contribute to the payments Spencer Trask may be required to make in respect of such liabilities. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to Spencer Trask, pursuant to the foregoing provisions or otherwise, the Company has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

***Transactions between InVivo and its CEO***

Beginning on December 31, 2005, InVivo's CEO and majority shareholder, Frank M. Reynolds, made a series of advances to InVivo to fund its continuing operations until it raised additional capital. Interest accrued on these advances at an annual rate of 8%. The largest aggregate amount of this indebtedness outstanding since the beginning of the fiscal year ended December 31, 2010 was \$145,985. Interest payments totaling \$2,373 were made during the fiscal year ended December 31, 2010. All amounts advanced to InVivo were paid back to Frank M. Reynolds before consummation of the Merger.



**Table of Contents****MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS****Market for Common Stock**

Our Common Stock is quoted on the OTC Bulletin Board under the symbol NVIV.OB. Our shares of Common Stock began being quoted on the OTC Bulletin Board under the symbol NVIV.OB 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 periods indicated below based upon reports of transactions on the OTC Bulletin Board.

| <b>Fiscal Quarter End</b> | <b>Low Bid</b> | <b>High Bid</b> |
|---------------------------|----------------|-----------------|
| December 31, 2010         | \$ 1.30        | \$ 4.00         |
| March 31, 2011            | \$ 0.75        | \$ 2.26         |
| June 30, 2011             | \$ 0.60        | \$ 1.10         |
| September 30, 2011        | \$ 0.60        | \$ 1.20         |

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 December 15, 2011, the closing bid price of our Common Stock as reported by the OTC Bulletin Board was \$2.04 per share.

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

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

 **Holders**

As of the date of this prospectus, there are approximately 237 record holders of 52,730,582 shares of the Common Stock. As of the date of this prospectus, 18,110,804 shares of Common Stock are issuable upon the exercise of outstanding warrants and 6,089,006 shares are exercisable upon the exercise of options.

 **Dividend Policy**

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.



**Table of Contents****DESCRIPTION OF SECURITIES**

*The following information describes our securities as well as certain provisions of our articles of incorporation and bylaws. This description is only a summary. You should also refer to our articles of incorporation and bylaws, which have been filed as exhibits to the registration statement of which this prospectus is a part.*

**Authorized Capital Stock**

As of December 9, 2011, our authorized capital stock consisted of 200,000,000 shares of Common Stock, par value \$0.00001 per share.

**Issued and Outstanding Capital Stock**

As of December 9, 2011, there were the following issued and outstanding securities of the Company:

52,730,582 shares of Common Stock;

Options to purchase 4,379,006 shares of Common Stock granted under the 2007 Plan;

Options to purchase 1,710,000 shares of Common Stock granted under the 2010 Plan;

Investor Warrants to purchase 12,364,733 shares of Common Stock at \$1.40 per share issued to the investors in the 2010 Private Placement and warrants issued to Spencer Trask and its employees to purchase 2,580,000 shares of Common Stock at a price of \$1.00 per share and 2,600,000 warrants exercisable at a price of \$1.40 per share; and

New Bridge Warrants issued to bridge investors in the bridge financing to purchase 450,000 shares of Common Stock at \$1.00 per share and 100,000 New Bridge Warrants exercisable at a price of \$1.00 per share issued to Spencer Trask in connection with the bridge financing.

A warrant for 16,071 shares issued to a commercial bank with an exercise price of \$1.40 per share.

**Reconciliation of Outstanding Capital Stock on a Pre and Post Merger Basis**

The following table reconciles the number of shares of the Company outstanding after the Merger with the number of shares of InVivo outstanding prior to the Merger.

|  |            |
|--|------------|
| InVivo Therapeutics Corporation Common Shares outstanding, pre merger as of September 30, 2010 | 2,261,862  |
| Merger Exchange Ratio  | 13.7706    |
|  | 31,147,197 |
| Less fractional shares not granted   | (7)        |
| Shares of ITHC issued to InVivo shareholders   | 31,147,190 |
| Existing Design Source Shares outstanding, pre merger  | 6,999,981  |
| Shares issued in 2010 Private Placement  | 13,000,000 |
| Shares issued in consideration for legal services  | 500,000    |

|  |            |
|--|------------|
| Common shares outstanding December 31, 2010  | 51,647,171 |
| Stock option exercised                       | 143,731    |
| Stock issued for investor relations services | 215,000    |
| Common shares outstanding September 30, 2011 | 52,005,902 |

**Description of Common Stock**

The holders of Common Stock are entitled to one vote per share on all matters submitted to a vote of the stockholders, including the election of directors. Generally, all matters to be voted on by stockholders must be approved by a majority (or, in the case of election of directors, by a plurality) of the votes entitled to be cast by

## **Table of Contents**

all shares of Common Stock that are present in person or represented by proxy. Except as otherwise provided by law, amendments to the articles of incorporation generally must be approved by a majority of the votes entitled to be cast by all outstanding shares of Common Stock. The amended and restated Articles of Incorporation do not provide for cumulative voting in the election of directors. The Common Stock holders will be entitled to such cash dividends as may be declared from time to time by the Board from funds available. Upon liquidation, dissolution or winding up of the Company, the Common Stock holders will be entitled to receive pro rata all assets available for distribution to such holders.

### **Warrants**

In connection with this offering, we will issue [ ] warrant for each share of Common Stock purchased or issued. Each warrant entitles the holder to purchase one share of Common Stock at an exercise price of \$[ ] per share. After the expiration of the [ ] exercise period, warrant holders will have no further rights to exercise such warrants.

The warrants may be exercised only for full shares of Common Stock. We will not issue fractional shares of Common Stock or cash in lieu of fractional shares of Common Stock. Warrant holders do not have any voting or other rights as a stockholder of our Company. The exercise price and the number of shares of Common Stock purchasable upon the exercise of each warrant are subject to adjustment upon the happening of certain events, such as stock dividends, distributions, and splits.

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

We may be or in the future we may become subject to Nevada's control share laws. A corporation is subject to Nevada's control share law if it has more than 200 stockholders, at least 100 of whom are stockholders of record and residents of Nevada, and if the corporation does business in Nevada, including through an affiliated corporation. This control share law may have the effect of discouraging corporate takeovers. The Company currently has less than 100 stockholders of record who are residents of Nevada.

The control share law focuses on the acquisition of a controlling interest, which means the ownership of outstanding voting shares that would be sufficient, but for the operation of the control share law, to enable the acquiring person to exercise the following proportions of the voting power of the corporation in the election of directors: (1) one-fifth or more but less than one-third; (2) one-third or more but less than a majority; or (3) a majority or more. The ability to exercise this voting power may be direct or indirect, as well as individual or in association with others.

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

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

In addition to the control share law, Nevada has a business combination law, which prohibits certain business combinations between Nevada corporations and interested stockholders for three years after the interested stockholder first becomes an interested stockholder, unless the corporation's board of directors approves the

## **Table of Contents**

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.

## **Indemnification of Officers and Directors**

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

Under NRS Section 78.751, advances for expenses may be made by agreement if the director or officer affirms in writing that he has met the standards for indemnification and will personally repay the expenses if it is determined that such officer or director did not meet those standards.

Our bylaws include an indemnification provision under which we have the power to indemnify our directors, officers, former directors and officers, employees and other agents (including heirs and personal representatives) against all costs, charges and expenses actually and reasonably incurred, including an amount paid to settle an action or satisfy a judgment to which a director or officer is made a party by reason of being or having been a director or officer of the Company. Our bylaws further provide for the advancement of all expenses incurred in connection with a proceeding upon receipt of an undertaking by or on behalf of such person to repay such amounts if it is determined that the party is not entitled to be indemnified under our bylaws. No advance will be made by the Company to a party if it is determined that the party acted in bad faith. These indemnification rights are contractual, and as such will continue as to a person who has ceased to be a director, officer, employee or other agent, and will inure to the benefit of the heirs, executors and administrators of such a person.

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

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

## **Transfer Agent and Registrar**

The transfer agent and registrar for our Common Stock is Continental Stock Transfer & Trust Company, 17 Battery Place, 8th Floor, New York, NY 10004.

## **OTC Bulletin Board Listing**

Our Common Stock is currently traded on the OTCQB operated by the OTC Markets Group ( OTCQB ) under the trading symbol NVIV.

**Table of Contents**

**PLAN OF DISTRIBUTION**

As of the date of this prospectus, we have not entered into any arrangements with any underwriter, broker-dealer or selling agent for the sale of the securities. We intend to engage one or more underwriters, broker-dealers or selling agents to sell the securities. We intend to compensate underwriters, broker-dealers or selling agents that sell securities in this offering with a cash commission to be agreed upon between us and any underwriters which we shall disclose prior to effectiveness. The offering will be presented by us primarily through mail, telephone, electronic transmission and direct meetings in those states in which we have registered the securities.

**Table of Contents**

**LEGAL MATTERS**

The validity of the securities being offered will be passed upon for us by BRL Law Group LLC, Boston, Massachusetts.

**EXPERTS**

Our balance sheets as of December 31, 2010 and 2009, and the related statements of operations, changes in stockholders' deficit and cash flows for the years then ended and for the period from November 28, 2005 (inception) to December 31, 2010 have been included herein and in the registration statement in reliance upon the report of Wolf & Company, P.C., independent registered public accountants, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

**WHERE YOU CAN FIND MORE INFORMATION**

We have filed a registration statement on Form S-1 with the SEC with respect to the securities we are offering by this prospectus. This prospectus does not include all of the information contained in the registration statement. You should refer to the registration statement and its exhibits for additional information. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document. We are subject to the information reporting requirements of the Exchange Act, and accordingly we are required to file annual, quarterly and special reports, proxy statements and other information with the SEC.

You can read our SEC filings, including the registration statement, on the Internet at the SEC's website at [www.sec.gov](http://www.sec.gov). You can also read and copy any document we file with the SEC at its public reference room at 100 F Street, N.E., Washington, D.C. 20549. You can also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference room.



**Table of Contents**

InVivo Therapeutics Holdings Corporation

Audited Financial Statements

Years Ended December 31, 2010 and 2009

and the Period from November 28, 2005

(Inception) through December 31, 2010

**CONTENTS**

|   | <b>Page</b> |
|---|-------------|
| <u>Report of Independent Registered Public Accounting Firm</u>  | F-2         |
| <b>Consolidated Financial Statements</b>  |             |
| <u>Consolidated Balance Sheets</u>  | F-3         |
| <u>Consolidated Statements of Operations</u>  | F-4         |
| <u>Consolidated Statements of Changes in Stockholders' Deficit</u>  | F-5         |
| <u>Consolidated Statements of Cash Flows</u>  | F-6-F-7     |
| <u>Notes to Consolidated Financial Statements</u>   | F-8-F-21    |
| <b>Unaudited Consolidated Financial Statements</b>  |             |
| <u>Consolidated Balance Sheets as of September 30, 2011 and December 31, 2010</u>                                   | F-22        |
| <u>Consolidated Statements of Operations for the three months and nine months ended September 30, 2011 and 2010</u> | F-23        |
| <u>Consolidated Statements of Cash Flows for the three months and nine months ended September 30, 2011 and 2010</u> | F-24        |
| <u>Notes to Financial Statements (Unaudited)</u>  | F-26        |

F-1

**Table of Contents**

**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, 2010 and 2009, 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, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2010 and 2009, and the results of its operations and its cash flows for the years then ended and for the period from November 28, 2005 (inception) to the December 31, 2010, in conformity with accounting principles generally accepted in the United States of America.

/s/ Wolf & Company, P.C.

Boston, Massachusetts

March 24, 2011, except for Notes 9, 11, 12 and 18 as to which the date is June 29, 2011.

**Table of Contents**

InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Consolidated Balance Sheets

|  | December 31,<br>2010<br>(Restated) | 2009               |
|--|------------------------------------|--------------------|
| <b>ASSETS:</b>   |                                    |                    |
| Current assets:  |                                    |                    |
| Cash and cash equivalents  | \$ 8,964,194                       | \$ 226,667         |
| Prepaid expenses   | 81,166                             | 10,898             |
| <b>Total current assets</b>  | <b>9,045,360</b>                   | <b>237,565</b>     |
| Property and equipment, net  | 280,181                            | 173,797            |
| Other assets   | 53,639                             | 58,639             |
| <b>Total assets</b>  | <b>\$ 9,379,180</b>                | <b>\$ 470,001</b>  |
| <b>LIABILITIES AND STOCKHOLDERS DEFICIT:</b>   |                                    |                    |
| Current liabilities:   |                                    |                    |
| Accounts payable   | \$ 336,945                         | \$ 81,175          |
| Accrued interest payable   |                                    | 283,608            |
| Derivative warrant liability   | 10,647,190                         |                    |
| Accrued expenses   | 247,547                            | 293,584            |
| <b>Total current liabilities</b>   | <b>11,231,682</b>                  | <b>658,367</b>     |
| Loans payable  |                                    | 590,985            |
| Convertible notes payable  |                                    | 2,840,000          |
| <b>Total liabilities</b>   | <b>11,231,682</b>                  | <b>4,089,352</b>   |
| Commitments and contingencies  |                                    |                    |
| Stockholders deficit:  |                                    |                    |
| Common stock , \$0.00001 par value; authorized 100,000,000 shares, issued and outstanding 51,647,171 and 26,259,515 shares outstanding at December 31, 2010 and 2009, respectively | 516                                | 263                |
| Additional paid-in capital   | 11,235,829                         | 1,558,283          |
| Deficit accumulated during the development stage   | (13,088,847)                       | (5,177,897)        |
| <b>Total stockholders deficit</b>  | <b>(1,852,502)</b>                 | <b>(3,619,351)</b> |
| <b>Total liabilities and stockholders deficit</b>  | <b>\$ 9,379,180</b>                | <b>\$ 470,001</b>  |

See notes to the consolidated financial statements.

**Table of Contents**

InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Consolidated Statements of Operations

|   | Years Ended    |                | Period from     |
|---|----------------|----------------|-----------------|
|   | December 31,   |                | November 28,    |
|   | 2010           | 2009           | 2005            |
|   | (Restated)     |                | (inception) to  |
|   |                |                | December 31,    |
|   |                |                | 2010            |
|   |                |                | (Restated)      |
| Operating expenses:   |                |                |                 |
| Research and development  | \$ 1,673,202   | \$ 1,807,908   | \$ 4,780,987    |
| General and administrative  | 1,724,102      | 835,515        | 3,695,665       |
| Total operating expenses  | 3,397,304      | 2,643,423      | 8,476,652       |
| Operating loss  | (3,397,304)    | (2,643,423)    | (8,476,652)     |
| Other income (expense):   |                |                |                 |
| Other income  |                | 383,000        | 383,000         |
| Interest income   | 3,379          | 282            | 11,290          |
| Interest expense  | (564,443)      | (255,737)      | (1,053,655)     |
| Derivatives losses  | (3,952,582)    |                | (3,952,582)     |
| Other income (expense), net   | (4,513,646)    | 127,545        | (4,611,947)     |
| Net loss  | \$ (7,910,950) | \$ (2,515,878) | \$ (13,088,599) |
| Net loss per share, basic and diluted                                   | \$ (0.24)      | \$ (0.10)      | \$ (0.49)       |
| Weighted average number of common shares outstanding, basic and diluted | 33,367,239     | 25,496,366     | 26,591,576      |

See notes to the consolidated financial statements.

**Table of Contents**

InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

## Consolidated Statements of Changes in Stockholders' Deficit

|  | Common Stock |        | Additional<br>Paid-in<br>Capital | Deficit<br>Accumulated<br>During the<br>Development<br>Stage | Total<br>Stockholders<br>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-cash 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 (Restated)   | 51,647,171   | \$ 516 | \$ 11,235,829                    | \$ (13,088,847)  | \$ (1,852,502)                   |

See notes to the consolidated financial statements.

**Table of Contents**

InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Consolidated Statements of Cash Flows

|  | Years Ended         |                    | Period from<br>November 28,<br>2005<br>(inception) to<br>December 31,<br>2010<br>(Restated) |
|--|---------------------|--------------------|---|
|  | December 31,        |                    |   |
|  | 2010<br>(Restated)  | 2009               |   |
| <b>Cash flows from operating activities:</b>                                       |                     |                    |   |
| Net loss   | \$ (7,910,950)      | \$ (2,515,878)     | \$ (13,088,599)   |
| <b>Adjustments to reconcile net loss to net cash used in operating activities:</b> |                     |                    |   |
| Depreciation and amortization expense  | 44,878              | 32,084             | 92,965  |
| Non-cash derivatives loss  | 3,952,582           |                    | 3,952,582   |
| Non-cash interest expense  | 528,535             | 221,899            | 962,834   |
| Share-based compensation expense   | 664,908             | 171,059            | 878,840   |
| <b>Changes in operating assets and liabilities:</b>                                |                     |                    |   |
| Prepaid expenses   | (70,268)            | 2,036              | (81,166)  |
| Other assets   |                     |                    | (75,000)  |
| Accounts payable   | 255,770             | (23,248)           | 336,945   |
| Accrued interest payable   | (67,931)            | 33,598             | (15,256)  |
| Accrued expenses   | (46,037)            | 179,426            | 247,547   |
| <b>Net cash used in operating activities</b>                                       | <b>(2,648,513)</b>  | <b>(1,899,024)</b> | <b>(6,788,308)</b>  |
| <b>Cash flows from investing activities:</b>                                       |                     |                    |   |
| Purchases of property and equipment  | (146,262)           | (174,898)          | (351,785)   |
| <b>Net cash used in investing activities</b>                                       | <b>(146,262)</b>    | <b>(174,898)</b>   | <b>(351,785)</b>  |
| <b>Cash flows from financing activities:</b>                                       |                     |                    |   |
| Proceeds from issuance of convertible notes payable                                | 200,000             | 1,580,000          | 4,181,000   |
| Proceeds from convertible bridge notes   | 500,000             |                    | 500,000   |
| (Repayment of) proceeds from loans payable   | (590,985)           | 513,800            |   |
| Proceeds from issuance of common stock and warrants                                | 11,423,287          |                    | 11,423,287  |
| <b>Net cash provided by financing activities</b>                                   | <b>11,532,302</b>   | <b>2,093,800</b>   | <b>16,104,287</b>   |
| Increase in cash and cash equivalents  | 8,737,527           | 19,878             | 8,964,194   |
| Cash and cash equivalents at beginning of period                                   | 226,667             | 206,789            |   |
| <b>Cash and cash equivalents at end of period</b>                                  | <b>\$ 8,964,194</b> | <b>\$ 226,667</b>  | <b>\$ 8,964,194</b>   |

(continued)

See notes to the consolidated financial statements.

**Table of Contents**

InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Consolidated Statements of Cash Flows (Concluded)

|  | Years Ended  |              | Period from<br>November 28,<br>2005<br>(inception) to<br>December 31,<br>2010 |
|--|--------------|--------------|---|
|  | December 31, |              |   |
|  | 2010         | 2009         |   |
| <b>Supplemental disclosure of cash flow information and non-cash transactions:</b>   |              |              |   |
| Cash paid for interest   | \$ 97,517    | \$           | \$ 97,517   |
| Conversion of convertible notes payable and accrued interest into common stock       | \$ 3,328,128 | \$ 1,344,366 | \$ 4,672,484  |
| Conversion of convertible bridge note payable and accrued interest into common stock | \$ 504,597   | \$           | \$ 504,597  |
| Beneficial conversion feature on convertible and bridge notes payable                | \$ 272,762   | \$           | \$ 134,410  |
| Fair value of warrants issued in connection with bridge notes payable                | \$ 178,726   | \$           | \$ 178,726  |
| Issuance of founders shares  | \$           | \$           | \$ 248  |

See notes to the consolidated financial statements.

F-7

---

**Table of Contents**

InVivo Therapeutics Holdings Corp.

(A Development Stage Company)

Notes to Consolidated Financial Statements

Years Ended December 31, 2010 and 2009, and the Period from

November 28, 2005 (Inception) through December 31, 2010

**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 Corporation (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 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 a reverse merger, and InVivo is deemed to be the acquirer and ongoing operating company. The Merger was recorded as a recapitalization of InVivo, 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 are 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 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 (see Note 11).

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



**Table of Contents**

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 acquiree in a reverse merger with a shell company, the historical financial statements of ITHC are not presented and these ITHC transactions are not reflected in the Company's accompanying consolidated financial statements.

**2. SIGNIFICANT ACCOUNTING POLICIES**

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

***Use of estimates***

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

***Principles of Consolidation***

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

***Cash and cash equivalents***

The Company considers all highly liquid investments with maturities of three months or less at the date of purchase to be cash equivalents.

***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, 2010 and 2009 was \$39,878 and \$27,084, 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 has been 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.

## **Table of Contents**

### ***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, 2010 and 2009, 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 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, 2010 or December 31, 2009.

### ***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, 2010 and 2009.

### ***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.

## **Table of Contents**

### ***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.

### ***Registration Payment Arrangements***

At each reporting date, the Company assesses the probability of it transferring consideration under its registration payment arrangements. If at any time it determines that such an event is probable and the amount can be reasonably estimated, the amount of such an obligation is recognized as a liability with a charge to earnings. Future changes in that liability will also be charged (credited) to earnings. At the date the Registration Rights Agreement (see Note 11) was entered into and at December 31, 2010, the Company did not conclude that it was probable that they will be obligated to transfer any consideration under the terms of this Registration Rights Agreement.

### ***Recent Accounting Pronouncements***

In October 2009, the Financial Accounting Standards Board ( FASB ) issued two related accounting pronouncements, Accounting Standards Update ( ASU ) 2009-13 and ASU 2009-14, relating to revenue recognition. One pronouncement provides guidance on allocating the consideration in a multiple-deliverable revenue arrangement and requires additional disclosure, while the other pronouncement provides guidance specific to revenue arrangements that include software elements. Both of these pronouncements are effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010 and both must be adopted together. The Company does not expect the adoption of these pronouncements to have a material impact on its consolidated financial statements.

In January 2010, the FASB issued ASU 2010-06, Fair Value Measurements and Disclosures (Topic 820), Improving Disclosures about Fair Value Measurements. This Update requires new disclosures and clarifies existing disclosures regarding recurring and nonrecurring fair value measurements to provide increased transparency to users of the financial statements. The new disclosures and clarification of existing disclosures are effective for interim and annual periods beginning after December 15, 2009, except for the disclosures pertaining to the roll forward of activity for Level 3 fair value measurements, which are effective for fiscal years beginning after December 15, 2010, and for interim periods within those fiscal years. The adoption of this Update on January 1, 2010 did not have a material impact on the Company's consolidated financial statements.

In April 2010, the FASB issued ASU 2010-17, Revenue Recognition - Milestone Method. ASU 2010-17 provides guidance in applying the milestone method of revenue recognition to research or development arrangements. Under this guidance, management may recognize revenue contingent upon the achievement of a milestone in its entirety, in the period in which the milestone is achieved, only if the milestone meets all the criteria within the guidance to be considered substantive. This ASU is effective on a prospective basis for research and development milestones achieved in fiscal years, beginning on or after June 15, 2010. Early adoption is permitted; however, the Company has elected to implement ASU 2010-17 prospectively, and as a result, the effect of this guidance will be limited to future transactions. The Company does not expect the adoption of this pronouncement to have a material impact on its consolidated financial statements.

**Table of Contents****3. PROPERTY AND EQUIPMENT**

Property and equipment consisted of the following:

|                                | December 31, |            |
|--------------------------------|--------------|------------|
|                                | 2010         | 2009       |
| Computer software and hardware | \$ 91,057    | \$ 47,668  |
| Research and lab equipment     | 260,728      | 157,855    |
| Less accumulated depreciation  | (71,604)     | (31,726)   |
|                                | \$ 280,181   | \$ 173,797 |

**4. OTHER ASSETS**

Other assets consist of a patent licensing fee paid to license intellectual property (see Note 16). The Company is amortizing the license fee to research and development over its 15-year term.

|                          | December 31, |           |
|--------------------------|--------------|-----------|
|                          | 2010         | 2009      |
| Patent licensing fee     | \$ 75,000    | \$ 75,000 |
| Accumulated amortization | (21,361)     | (16,361)  |
|                          | \$ 53,639    | \$ 58,639 |

Amortization expense was \$5,000 in each of the years ended December 31, 2010 and 2009.

**5. ACCRUED EXPENSES**

Accrued expenses consisted of the following:

|                        | December 31, |            |
|------------------------|--------------|------------|
|                        | 2010         | 2009       |
| Other accrued expenses | \$ 45,053    | \$ 138,750 |
| Accrued payroll        | 179,629      | 18,969     |
| Accrued vacation       | 22,865       | 15,865     |
| Deferred compensation  |              | 120,000    |
|                        | \$ 247,547   | \$ 293,584 |

Deferred compensation represented amounts owed to the Chief Executive Officer ( CEO ) with respect to annual bonuses granted but not paid. All deferred compensation was paid in the year ended December 31, 2010.

**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.

## Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form S-1

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.

F-12

**Table of Contents**

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, 2010 |               |         |               |
|------------------------------|-------------------|---------------|---------|---------------|
|                              | Level 1           | Level 2       | Level 3 | Fair Value    |
| <b>Liabilities:</b>          |                   |               |         |               |
| Derivative warrant liability | \$                | \$ 10,647,190 |         | \$ 10,647,190 |

|                              | December 31, 2009 |         |         |            |
|------------------------------|-------------------|---------|---------|------------|
|                              | Level 1           | Level 2 | Level 3 | Fair Value |
| <b>Liabilities:</b>          |                   |         |         |            |
| Derivative warrant liability | \$                | \$      |         | \$         |

**7. LOANS PAYABLE**

Loans payable consisted of the following:

|  | December 31, |            |
|--|--------------|------------|
|  | 2010         | 2009       |
| Advances from related party                    | \$           | \$ 90,985  |
| Note payable-Massachusetts Life Science Center |              | 500,000    |
|  | \$           | \$ 590,985 |

Advances from related party represent cash advances received from CEO and majority shareholder which permitted the Company to continue to fund its operations until it raised additional capital. Interest accrued on these advances at an annual rate of 8%. Interest expense related to Advances from related party was \$3,227 and \$8,437 in the years ended December 31, 2010 and 2009, respectively.

The Company issued a \$500,000 Note Payable in June 2009 to the Massachusetts Life Science Center, an independent public agency of the State of Massachusetts. The Company received the \$500,000 of funding from the Massachusetts Life Science Accelerator Program which was established for the purpose of providing seed capital to promising early stage life science companies. The terms of the Note Payable called for full repayment upon the earlier of five years, the sale of the Company or a financing that raises minimum net proceeds of \$5,000,000. Interest accrued on the Note Payable at an annual rate of 10% and is payable at maturity. Interest expense related to the Note Payable was \$42,726, and \$25,205 for the years ended December 31, 2010 and 2009, respectively. In October 2010, the \$500,000 loan was repaid together with accrued interest of \$67,931.

**8. CONVERTIBLE NOTES PAYABLE**

Since inception, the Company issued Convertible Notes Payable to investors totaling \$4,181,000. In the years ended December 31, 2010 and 2009, these notes provided cash proceeds of \$200,000 and \$1,580,000, respectively. The terms of the Convertible Notes Payable include interest at 8% and stipulated that the notes



## **Table of Contents**

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).

During the year ended December 31, 2009, Convertible Notes Payable with a principal balance of \$1,141,000 and accrued interest payable of \$203,366 converted at maturity into 1,472,435 shares of Common Stock.

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 and 2009, the Company accrued interest expense on the notes of \$62,385 and \$169,573, respectively.

## **9. 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, 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



## **Table of Contents**

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 11).

## **10. 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, 2010 and 2009, the Company had federal and Massachusetts net operating loss carryforwards of approximately \$8,719,000, and \$5,491,000, respectively, of which federal carryforwards will expire in varying amounts beginning in 2021. Massachusetts net operating losses begin to expire in 2011. Utilization of net operating losses may be subject to substantial annual limitations due to the change in ownership provisions of the Internal Revenue Code, and similar state provisions. The annual limitations may result in the expiration of net operating losses before utilization. The Company also had research and development tax credit carryforwards at December 31, 2010 and 2009 of approximately \$238,000 and \$154,000, respectively, which will begin to expire in 2018 unless previously utilized.

**Table of Contents**

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

|  | December 31,     |                  |
|--|------------------|------------------|
|  | 2010             | 2009             |
| Net operating loss carryforward              | \$ 3,016,062     | \$ 1,612,965     |
| Research and development credit carryforward | 120,315          | 154,077          |
| Stock based Compensation                     | 382,295          | 86,150           |
| Deferred compensation                        | 52,200           | 48,324           |
| Accrued interest                             |                  | 114,209          |
| Charitable contributions                     | 17,751           | 3,533            |
| <b>Subtotal</b>                              | <b>3,588,623</b> | <b>2,019,258</b> |
| Valuation allowance                          | (3,588,623)      | (2,019,258)      |
| <b>Net deferred tax asset</b>                | <b>\$</b>        | <b>\$</b>        |

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, 2010 and 2009, the valuation allowance increased by \$1,569,000 and \$1,044,000, respectively.

The Company has no uncertain tax positions at December 31, 2010 and 2009 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 the 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, |           |
|---|--------------|-----------|
|   | 2010         | 2009      |
| Statutory tax rate                                | 34.0%        | 34.0%     |
| State taxes, net of federal benefit               | 2.7%         | 6.2%      |
| Permanent differences (derivative loss and other) | -19.3%       | 0.2%      |
| R&D tax credit                                    | 0.7%         | 1.6%      |
| Increase in valuation reserve                     | -18.1%       | -41.6%    |
| <b>Effective tax rate</b>                         | <b>0%</b>    | <b>0%</b> |

**11. COMMON STOCK**

The Company has authorized 100,000,000 shares of Common Stock, \$0.00001 par value per share, of which 51,647,171 shares and 26,259,515 shares were issued and outstanding as of December 31, 2010 and 2009, 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.

Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form S-1

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.

F-16

---

**Table of Contents**

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 8).

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 9). 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.

***Registration Rights Agreement***

In connection with the Offering, the Company entered into a Registration Rights Agreement with the private placement investors, whereby the Company agreed to register common stock as defined in the agreement. The Company is required to file within 90 days of the date of the final closing (the Filing Deadline ), a registration statement registering for resale all shares of Common Stock issued in the private placement, including Common Stock (i) included in the Units; and (ii) issuable upon exercise of the Investor Warrants. The Company has agreed to use its reasonable efforts to have the registration statement declared effective within 180 days of filing the registration statement (the Effectiveness Deadline ). If the Registration Statement is not filed on or before the Filing Deadline or not declared effective on or before the Effectiveness Deadline, the Company shall pay to each holder of registrable securities an amount in cash equal to one-half of one percent (0.5%) of such holder's investment in the Offering or in the Bridge Financing on every thirty (30) day anniversary of such Filing Deadline or Effectiveness Deadline failure until such failure is cured. The payment amount shall be prorated for partial thirty (30) day periods. The maximum aggregate amount of payments to be made by the Company as the result of such failures, whether by reason of a Filing Deadline failure, Effectiveness Deadline failure or any combination thereof, shall be an amount equal to 9% of each Unit holder's investment amount. The Company shall keep the Registration Statement effective for one (1) year from the date it is declared effective by the SEC or until Rule 144 of the Securities Act is available to the investors with respect to all of their shares, whichever is earlier.

**Table of Contents****Common Stock Reserves**

As of December 31, 2010, the Company had the following reserves established for the future issuance of Common Stock as follows:

|   |                   |
|---|-------------------|
| Reserve for the exercise of warrants      | 18,800,000        |
| Reserve for the exercise of stock options | 9,415,557         |
| <b>Total Reserves</b>                     | <b>28,215,557</b> |

**12. DERIVATIVE INSTRUMENTS**

Certain warrants issued to the investors in the Offering, the Bridge Note investors and the Placement Agent (see Notes 10 and 11) 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, 2010 was \$10,647,190 and is included as a derivative warrant liability, a current liability. Changes in fair value of the derivative financial instruments are recognized currently in the Statement of Operations as a derivatives gain or loss. The warrant derivative loss for the year ended December 31, 2010 was \$3,952,582 and was included in other income (expense) in the consolidated statement of operations. There was no derivatives loss for the year ended December 31, 2009.

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

|                         |                      |
|-------------------------|----------------------|
|                         | December 31,<br>2010 |
| Risk-free interest rate | 2.0%                 |
| Expected dividend yield | 0%                   |
| Contractual Term        | 4.7-4.9 years        |
| Expected volatility     | 50%                  |

The primary underlying risk exposure pertaining to the warrants is the change in fair value of the underlying Common Stock for each reporting period.

**13. 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, 2010, there were options to purchase an aggregate of 5,915,557 shares of Common Stock outstanding under the 2007 Plan and no shares available for future grants under the 2007 Plan.

On October 25, 2010, the Company's Board of Directors adopted the 2010 Equity Incentive Plan, subject to shareholder approval (the "2010 Plan"). The 2010 Plan provides for grants of incentive stock options to employees and nonqualified stock options and restricted Common Stock to employees, consultants and non-employee directors of the Company. As of December 31, 2010, the number of shares authorized for issuance under the 2010 Plan was 3,500,000 shares. As of December 31, 2010, there were options to purchase an aggregate of 280,000 shares of Common Stock outstanding under the 2010 Plan and 3,220,000 shares available for future grants under the 2010 Plan. If shareholder approval is not obtained by October 25, 2011, all awards granted under the 2010 Plan will terminate. In addition, no award under the 2010 Plan will become exercisable until shareholder approval has been obtained and a registration statement on Form S-8 has been filed with the SEC.



**Table of Contents**

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 during the years ended December 31, 2010 and 2009, the Company recorded non-cash, stock-based compensation expense of \$664,908 and \$171,059, respectively, each net of estimated 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 Company's stock plans, all of which qualify as plain vanilla, is based on the average of the contractual term (generally 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 to employees were as follows:

|                                 | December 31,  |            |
|---------------------------------|---------------|------------|
|                                 | 2010          | 2009       |
| Risk-free interest rate         | 1.63% - 3.05% | 2.68%      |
| Expected dividend yield         | 0%            | 0%         |
| Expected term (employee grants) | 6.25 years    | 6.25 years |
| Expected volatility             | 49.12%        | 50.1110%   |

A summary of option activity under the Company's stock plans and options granted to officers of the Company outside any plan as of December 31, 2010 and 2009 and changes during the years 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, 2008 | 2,980,729 | \$ 0.07                         |  |                           |
| Granted                          | 963,941   | \$ 0.86                         |  |                           |
| Forfeited                        | (82,624)  | \$ 0.07                         |  |                           |
| Outstanding at December 31, 2009 | 3,862,046 | \$ 0.27                         |  |                           |
| Granted                          | 2,333,511 | \$ 1.13                         |  |                           |
| Outstanding at December 31, 2010 | 6,195,557 | \$ 0.59                         | 8.31   | \$ 10,322,073             |
| Vested at December 31, 2010      | 2,406,112 | \$ 0.15                         | 7.04   | \$ 5,072,223              |

The weighted average grant-date fair value of options granted during the years ended December 31, 2010 and 2009 was \$0.55 and \$0.45 per share, respectively. The total fair value of options that vested in the years ended December 31, 2010 and 2009 was \$962,810 and \$346,976, respectively. As of December 31, 2010 and 2009, there was approximately \$2,236,133 and \$1,026,595 of total unrecognized compensation expense, respectively, related to non-vested share-based option compensation arrangements. The unrecognized compensation expense is estimated to be recognized over a period of 2.95 and 2.72 years at December 31, 2010 and 2009, respectively.

**Table of Contents****14. WARRANTS**

The following presents information about warrants to purchase Common Stock issued and outstanding at December 31, 2010:

| Year Issued                     | Number of Warrants | Exercise Price | Date of Expiration     |
|---------------------------------|--------------------|----------------|------------------------|
| 2010                            | 15,600,000         | \$ 1.40        | 10/26/2015 - 12/3/2015 |
| 2010                            | 3,200,000          | 1.00           | 9/26/2015 - 12/3/2015  |
| <b>Total</b>                    | <b>18,800,000</b>  |                |                        |
| Weighted average exercise price |                    | \$ 1.33        |                        |
| Weighted average life in years  |                    |                | 4.8                    |

**15. 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 but has elected not to do so.

**16. 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 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. 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 (see Note 3) and is required to pay certain annual maintenance fees, milestone payments and royalties. All costs associated with maintenance of the CMCC License are expensed as incurred.

**17. COMMITMENTS AND CONTINGENCIES*****Legal Settlement***

In 2009, the Company filed a lawsuit against a party alleging damages from a breach of a contract under which the party was providing services to the Company. In exchange for a payment of \$383,000 from the party, the Company agreed to dismiss the lawsuit. The \$383,000 received was recorded as other income in the Statement of Operations in the year ended December 31, 2009.

***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.

Pursuant to the terms of the non-cancelable lease agreement in effect at December 31, 2010, future minimum rent commitments are as follows:

| Year Ended December 31, |           |
|-------------------------|-----------|
| 2011                    | \$ 47,061 |
| 2012                    | 43,139    |



Total

\$ 90,200

F-20

**Table of Contents**

Total rent expense for the years ended December 31, 2010 and 2009, including month-to-month leases, was approximately \$270,000 and \$123,000.

**18. RESTATEMENT**

The Company is restating its 2010 financial statements to correct an error related to the accounting for derivative liabilities. The error related to the process of allocating the proceeds of a financing to two instruments when one of those instruments was a derivative liability. Originally, the Company allocated the proceeds using the relative fair value of the two instruments with the derivative liability being recorded at its fair value and any difference between the relative fair value and fair value being charged to a derivative gain or loss upon issuance. The purpose of this restatement is to first allocate the proceeds to the derivative to the extent of its fair value with the residual allocated to the common stock.

The December 31, 2010 balance sheet line items were impacted by the following amounts:

|  |                |
|--|----------------|
| Additional paid-in capital                       | \$ (1,146,312) |
| Deficit accumulated during the development stage | 1,146,312      |

The statement of operations line items were impacted as follows:

|   | Year Ended<br>December 31, 2010 | Period from November 28,<br>2005 (inception) to<br>December 31, 2010 |
|---|---------------------------------|--|
| Derivatives losses                          | \$ 1,146,312                    | \$ 1,146,312   |
| Net loss                                    | \$ 1,146,312                    | \$ 1,146,312   |
| Net loss per share, basic and fully diluted | \$ 0.03                         | \$ 0.05  |

The statement of changes in stockholders' equity for the year ended December 31, 2010 line items were impacted as follows:

|  |                |
|--|----------------|
| Issuance of common stock in private Placement, net of stock issuance costs of \$2,072,117 and non-cash stock issuance costs of \$5,369,570 | \$ (1,146,312) |
| Net loss   | 1,146,312      |

**19. SUBSEQUENT EVENT**

Subsequent to December 31, 2010, the Company issued 27,541 shares of Common Stock upon exercise of stock options.

**Table of Contents****InVivo Therapeutics Holdings Corp.****(A Developmental Stage Company)****Consolidated Balance Sheets**

|  | As of                              |                      |
|--|------------------------------------|----------------------|
|  | September 30,<br>2011<br>Unaudited | December 31,<br>2010 |
| <b>ASSETS:</b>   |                                    |                      |
| Current assets:  |                                    |                      |
| Cash and cash equivalents  | \$ 3,686,929                       | \$ 8,964,194         |
| Restricted cash  | 155,000                            |                      |
| Prepaid expenses   | 119,523                            | 81,166               |
| Total current assets   | 3,961,452                          | 9,045,360            |
| Property and equipment, net  | 520,992                            | 280,181              |
| Other assets   | 121,764                            | 53,639               |
| Total assets   | \$ 4,604,208                       | \$ 9,379,180         |
| <b>LIABILITIES AND STOCKHOLDERS DEFICIT:</b>   |                                    |                      |
| Current liabilities:   |                                    |                      |
| Accounts payable   | \$ 553,807                         | \$ 336,945           |
| Loan payable-current portion   | 41,666                             |                      |
| Capital lease payable-current portion  | 32,906                             |                      |
| Derivative warrant liability   | 4,087,355                          | 10,647,190           |
| Accrued expenses   | 359,081                            | 247,547              |
| Total current liabilities  | 5,074,815                          | 11,231,682           |
| Loan payable-less current portion  | 76,391                             |                      |
| Capital lease payable-less current portion   | 43,281                             |                      |
| Total liabilities  | 5,194,487                          | 11,231,682           |
| Commitments and contingencies  |                                    |                      |
| Stockholders' deficit:   |                                    |                      |
| Common stock, \$0.00001 par value, authorized 200,000,000 and 100,000,000 shares at September 30, 2011 and December 31, 2010, respectively; issued and outstanding 52,005,902 and 51,647,171 shares at September 30, 2011 and December 31, 2010, respectively. | 520                                | 516                  |
| Additional paid-in capital   | 12,079,127                         | 11,235,829           |
| Deficit accumulated during the development stage   | (12,669,926)                       | (13,088,847)         |
| Total stockholders' deficit  | (590,279)                          | (1,852,502)          |
| Total liabilities and stockholders' deficit  | \$ 4,604,208                       | \$ 9,379,180         |

See notes to the consolidated financial statements.



**Table of Contents****InVivo Therapeutics Holdings Corp.****(A Developmental Stage Company)****Consolidated Statements of Operations****(Unaudited)**

|  | Three Months Ended<br>September 30, |              | Nine Months Ended<br>September 30, |                | Period from<br>November 28,<br>2005<br>(inception) to<br>September 30,<br>2011 |
|--|-------------------------------------|--------------|------------------------------------|----------------|--|
|  | 2011                                | 2010         | 2011                               | 2010           |  |
| Operating expenses:  |                                     |              |                                    |                |  |
| Research and development   | \$ 1,016,865                        | \$ 324,626   | \$ 3,045,426                       | \$ 950,059     | \$ 7,826,413   |
| General and administrative                                       | 1,196,455                           | 424,050      | 3,095,877                          | 974,942        | 6,791,542  |
| Total operating expenses   | 2,213,320                           | 748,676      | 6,141,303                          | 1,925,001      | 14,617,955   |
| Operating loss   | (2,213,320)                         | (748,676)    | (6,141,303)                        | (1,925,001)    | (14,617,955)   |
| Other income (expense):  |                                     |              |                                    |                |  |
| Other income   |                                     |              |                                    |                | 383,000  |
| Interest income  | 4,778                               | 47           | 7,539                              | 267            | 18,829   |
| Interest expense   |                                     | (36,931)     | (7,150)                            | (285,259)      | (1,060,805)  |
| Derivatives gain (loss)  | 5,275,591                           | (51,195)     | 6,559,835                          | (51,195)       | 2,607,253  |
| Other income (expense), net                                      | 5,280,369                           | (88,079)     | 6,560,224                          | (336,187)      | 1,948,277  |
| Net income (loss)  | \$ 3,067,049                        | \$ (836,755) | \$ 418,921                         | \$ (2,261,188) | \$ (12,669,678)  |
| Net income (loss) per share, basic                               | \$ 0.06                             | \$ (0.03)    | \$ 0.01                            | \$ (0.08)      | \$ (0.43)  |
| Net income (loss) per share, diluted                             | \$ 0.06                             | \$ (0.03)    | \$ 0.01                            | \$ (0.08)      | \$ (0.43)  |
| Weighted average number of common shares<br>outstanding, basic   | 51,889,111                          | 31,147,190   | 51,743,138                         | 29,378,512     | 29,782,271   |
| Weighted average number of common shares<br>outstanding, diluted | 54,269,856                          | 31,147,190   | 54,198,981                         | 29,378,512     | 29,782,271   |

See notes to the consolidated financial statements.

**Table of Contents****InVivo Therapeutics Holdings Corp.****(A Developmental Stage Company)****Consolidated Statements of Cash Flows****(Unaudited)**

|  | <b>Nine Months Ended</b> |                    | <b>Period from</b>    |
|--|--------------------------|--------------------|-----------------------|
|  | <b>September 30,</b>     |                    | <b>November 28,</b>   |
|  | <b>2011</b>              |                    | <b>2005</b>           |
|  | <b>September 30,</b>     |                    | <b>(inception) to</b> |
|  | <b>2011</b>              | <b>2010</b>        | <b>September 30,</b>  |
|  | <b>2011</b>              |                    |                       |
| <b>Cash flows from operating activities:</b>                                       |                          |                    |                       |
| Net income (loss)  | \$ 418,921               | \$ (2,261,188)     | \$ (12,669,678)       |
| <b>Adjustments to reconcile net loss to net cash used in operating activities:</b> |                          |                    |                       |
| Depreciation and amortization expense  | 101,599                  | 36,136             | 194,564               |
| Non-cash derivatives (gain) loss   | (6,559,835)              | 51,195             | (2,607,253)           |
| Non-cash interest expense  |                          | 236,286            | 962,834               |
| Common stock issued for services   | 200,676                  |                    | 200,676               |
| Share-based compensation expense   | 622,141                  | 364,128            | 1,500,981             |
| <b>Changes in operating assets and liabilities:</b>                                |                          |                    |                       |
| Restricted cash  | (155,000)                |                    | (155,000)             |
| Prepaid expenses   | (28,306)                 | (40,117)           | (109,472)             |
| Other assets   | (75,000)                 |                    | (150,000)             |
| Accounts payable   | 216,862                  | 58,333             | 553,807               |
| Accrued interest payable   |                          | 13,968             | (15,256)              |
| Accrued expenses   | 111,534                  | (207,807)          | 359,081               |
| <b>Net cash used in operating activities</b>                                       | <b>(5,146,408)</b>       | <b>(1,749,066)</b> | <b>(11,934,716)</b>   |
| <b>Cash flows from investing activities:</b>                                       |                          |                    |                       |
| Purchases of property and equipment  | (241,995)                | (24,610)           | (593,780)             |
| <b>Net cash used in investing activities</b>                                       | <b>(241,995)</b>         | <b>(24,610)</b>    | <b>(593,780)</b>      |
| <b>Cash flows from financing activities:</b>                                       |                          |                    |                       |
| Proceeds from issuance of convertible notes payable                                |                          | 700,000            | 4,181,000             |
| Proceeds from convertible bridge notes   |                          |                    | 500,000               |
| (Repayment of) proceeds from loans payable   | 118,057                  | (90,985)           | 118,057               |
| Principal payments on capital lease obligation                                     | (17,353)                 |                    | (17,353)              |
| Proceeds from issuance of common stock and warrants                                | 10,434                   | 1,000,000          | 11,433,721            |
| <b>Net cash provided by financing activities</b>                                   | <b>111,138</b>           | <b>1,609,015</b>   | <b>16,215,425</b>     |
| <b>(Decrease) Increase in cash and cash equivalents</b>                            | <b>(5,277,265)</b>       | <b>(164,661)</b>   | <b>3,686,929</b>      |
| Cash and cash equivalents at beginning of period                                   | 8,964,194                | 226,667            |                       |

Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form S-1

|  |           |    |        |    |           |
|--|-----------|----|--------|----|-----------|
| Cash and cash equivalents at end of period | 3,686,929 | \$ | 62,006 | \$ | 3,686,929 |
|--|-----------|----|--------|----|-----------|

(continued)

See notes to the consolidated financial statements.

F-24

**Table of Contents****InVivo Therapeutics Holdings Corp.****(A Developmental Stage Company)****Consolidated Statements of Cash Flows (Concluded)****(Unaudited)**

|  | Nine Months Ended<br>September 30, |              | Period from<br>November 28,<br>2005<br>(inception) to<br>September 30,<br>2011 |
|--|------------------------------------|--------------|--|
|  | 2011                               | 2010         |  |
| Supplemental disclosure of cash flow information and non-cash transactions:          |                                    |              |  |
| Cash paid for interest   | \$ 5,077                           | \$ 29,586    | \$ 97,517  |
| 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   |
| Asset acquired through capital lease obligation                                      | \$ 93,540                          | \$           | \$ 93,540  |
| Beneficial conversion feature on convertible and bridge notes payable                | \$                                 | \$ 134,410   | \$ 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   |

See notes to the consolidated financial statements.



---

**Table of Contents**

**InVivo Therapeutics Holdings Corp.**

**(A Development Stage Company)**

**Notes to Consolidated Financial Statements**

**Period Ended September 30, 2011 (Unaudited)**

**1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION**

***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 Corporation (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 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

---

**Table of Contents**

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.

***Basis of Presentation***

The accompanying unaudited consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States ( GAAP ) consistent with those applied in, and should be read in conjunction with, the Company's audited financial statements and related footnotes for the year ended December 31, 2010 included in the Company's Annual Report on Form 10-K, as amended, as filed with the United States Securities and Exchange Commission ( SEC ). The unaudited consolidated financial statements reflect all adjustments, consisting only of normal recurring adjustments, which are, in the opinion of management, necessary for a fair presentation of the Company's financial position as of September 30, 2011 and its results of operations and cash flows for the interim periods presented and are not necessarily indicative of results for subsequent interim periods or for the full year. The interim financial statements do not include all of the information and footnotes required by GAAP for complete financial statements as allowed by the relevant SEC rules and regulations; however, the Company believes that its disclosures are adequate to ensure that the information presented is not misleading.

**2. CASH AND CASH EQUIVALENTS**

As of September 30, 2011, the Company held approximately \$3,700,000 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 September 30, 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 \$3,370,000 as of September 30, 2011. Restricted cash represents a \$105,000 security deposit related to the Company's credit card account and a \$50,000 minimum balance in a checking account that is required as part of a loan agreement.

**3. FAIR VALUE 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 unobservable inputs to 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.

**Table of Contents**

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:

|                              | September 30, 2011 |              |         | Fair Value   |
|------------------------------|--------------------|--------------|---------|--------------|
|                              | Level 1            | Level 2      | Level 3 |              |
| <b>Liabilities:</b>          |                    |              |         |              |
| Derivative warrant liability | \$                 | \$ 4,087,355 |         | \$ 4,087,355 |

  

|                              | December 31, 2010 |               |         | Fair Value    |
|------------------------------|-------------------|---------------|---------|---------------|
|                              | Level 1           | Level 2       | Level 3 |               |
| <b>Liabilities:</b>          |                   |               |         |               |
| Derivative warrant liability | \$                | \$ 10,647,190 |         | \$ 10,647,190 |

**4. COMMITMENTS*****Operating Lease Commitment***

The Company leases approximately 1,200 square feet of laboratory and office space in Medford, Massachusetts under a lease expiring November 14, 2012. Future minimum lease payments under this operating lease are approximately as follows:

|                                   | Amount    |
|-----------------------------------|-----------|
| For the years ending December 31, |           |
| 2011                              | \$ 11,976 |
| 2012                              | 43,139    |
| Total                             | \$ 55,115 |

The Company's rent expense under this lease was approximately \$12,000 and \$39,000 for the three and nine months ended September 30, 2011. Total rent expense in these periods was approximately \$88,000 and \$267,000, respectively.

***Other Commitments***

In February 2011, the Company entered into an agreement with a contract research organization to perform non-human clinical trials. The agreement requires total payments of \$850,000 of which \$425,000 was paid upon execution of the contract. The remaining \$425,000 is expected to be paid in the fourth quarter of 2011.

***Registration Payment Arrangements***

In connection with the Merger (see Note 1), the Company completed a private placement of 13,000,000 Units of its securities. The Company entered into a Registration Rights Agreement with the private placement investors, whereby the Company agreed to register common stock as defined in the agreement. The Company was required to file within 90 days of the date of the final closing (the Filing Deadline), a registration statement registering for resale all shares of Common Stock issued in the private placement, including Common Stock (i) included in the Units; and (ii) issuable upon exercise of the Investor Warrants. On July 29, 2011, the SEC declared that the Company's Registration Statement was effective. The Company has an on-going responsibility to maintain the effectiveness of the Registration Statement until the earlier of: (i) one year from the date of effectiveness or, (ii) when Rule 144 of the Securities Act is available to the private placement investors.



**Table of Contents****5. CAPITAL LEASE OBLIGATION**

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:

|                       |                       |
|-----------------------|-----------------------|
|                       | September 30,<br>2011 |
| Capital lease payable | \$ 76,187             |
| Less: current portion | (32,906)              |
|                       | \$ 43,281             |

The total value of the laboratory equipment acquired under this capital lease agreement was \$124,151. 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 three and nine months ended September 30, 2011, interest expense recorded on the capital lease was \$949 and \$2,973, respectively. For the three and nine months ended September 30, 2011, depreciation expense was \$6,208 and \$16,553, respectively.

**6. 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, 2011. 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 a \$7,500 commitment fee 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 in the three and nine months ended September 30, 2011 was \$2,073. As of September 30, 2011, there was a total of \$125,000 advanced on the equipment line of credit. 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. The loan payable at September 30, 2011 consisted of the following:

|                       |                       |
|-----------------------|-----------------------|
|                       | September 30,<br>2011 |
| Equipment Loan        | \$ 118,057            |
| Less: current portion | (41,666)              |
|                       | \$ 76,391             |

Interest expense related to the loan payable in the three and nine months ended September 30, 2011 was \$1,433.

**7. COMMON STOCK**

The Company has authorized 200,000,000 shares of Common Stock, \$0.00001 par value per share, of which 52,005,902 shares and 51,647,171 shares were issued and outstanding as of September 30, 2011 and December 31, 2010, respectively.

In February 2011, the Company issued 27,541 shares of Common Stock upon the exercise of stock options and received cash proceeds of \$1,999.

Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form S-1

In June 2011, the Company issued 65,000 unregistered shares with a fair value of approximately \$55,000 to an investor relations firm in exchange for services provided.

F-29

**Table of Contents**

In August 2011, the Company issued 150,000 unregistered shares with a fair value of approximately \$142,500 to a firm providing investor relations services.

On August 5, 2011, Company issued 116,190 shares of Common Stock upon the exercise of stock options and received cash proceeds of \$8,435.

**8. DERIVATIVE INSTRUMENTS**

Derivative financial instruments are recognized as a liability on the consolidated balance sheet and measured at fair value.

At September 30, 2011 and December 31, 2010, the Company had outstanding warrants to purchase 18,800,000 shares of its Common Stock which are considered to be derivative instruments since the agreements contain provisions that include anti-dilution protection and, under certain conditions, grant the right to the holder to request the Company to repurchase the warrant. 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 September 30, 2011 and December 31, 2010 were \$4,087,355 and \$10,647,190, respectively. 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 gain for the three and nine months ended September 30, 2011 was \$5,275,590 and \$6,559,834, respectively, and was included in other income (expense) in the consolidated statement of operations. The warrant derivative loss for the three and nine months ended September 30, 2010 was \$51,195.

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

|                         | As of<br>September 30,<br>2011 |
|-------------------------|--------------------------------|
| Risk free interest rate | .96%                           |
| Expected dividend yield | 0%                             |
| Contractual term        | 3.9-4.2 years                  |
| Expected volatility     | 67%                            |

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 nine months ended September 30, 2011:

|  | Nine Months<br>Period Ended<br>September 30, 2011 |
|--|---|
| Balance as of December 31, 2010                                | \$ 10,647,190                                     |
| Change in fair value of warrants with anti-dilution provisions | (6,559,835)                                       |
| Balance as of September 30, 2011                               | \$ 4,087,355                                      |

**9. 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





**Table of Contents**

employees, officers, directors, consultants and advisors. As of September 30, 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 September 30, 2011, the number of shares authorized for issuance under the 2010 Plan was 3,500,000 shares. As of September 30, 2011, there were options to purchase an aggregate of 940,000 shares of Common Stock outstanding under the 2010 Plan and 2,560,000 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 three and nine months ended September 30, 2011, the Company recorded non-cash, stock-based compensation expense of \$111,799 and \$622,141, 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 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 to employees were as follows:

|                                 | As of<br>September 30,<br>2011 |
|---------------------------------|--------------------------------|
| Risk-free interest rate         | 1.89%                          |
| Expected dividend yield         | 0%                             |
| Expected term (employee grants) | 6.21 years                     |
| Expected volatility             | 67%                            |

**Table of Contents**

A summary of option activity under the Plans and options granted to officers of the Company outside any plan as of September 30, 2011 and changes during the nine months then ended is presented below:

| Options                           | Shares      | Weighted<br>Average<br>Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term in<br>Years | Aggregate<br>Intrinsic<br>Value |
|-----------------------------------|-------------|--|---|---------------------------------|
| Outstanding at December 31, 2010  | 6,195,557   | \$ 0.59                                  |   |                                 |
| Granted                           | 580,000     | \$ 1.08                                  |   |                                 |
| Forfeited                         | (1,392,821) | \$ 0.93                                  |   |                                 |
| Exercised                         | (143,731)   | \$ 0.07                                  |   |                                 |
| Outstanding at September 30, 2011 | 5,239,005   | \$ 0.57                                  | 7.48  | \$ 1,609,324                    |
| Exercisable at September 30, 2011 | 2,808,842   | \$ 0.27                                  | 6.47  | \$ 1,404,070                    |

The weighted average grant-date fair value of options granted during the nine months ended September 30, 2011 was \$0.54 per share. The total fair value of options that vested in the nine months ended September 30, 2011 was \$1,404,070. As of September 30, 2011, there was approximately \$933,637 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 2.84 years at September 30, 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 three and nine months ended September 30, 2011, the Company amortized \$2,925 of stock compensation expense.

In September 2011, the Company entered into an employment agreement for a Chief Science Officer. The agreement requires the Company to issue 775,000 stock options at an exercise price equal to the closing price of the common stock on the date of grant upon commencement of employment which is anticipated to be December 2011. These options will have a vesting period of four years.

**10. WARRANTS**

The following presents information about warrants to purchase Common Stock issued and outstanding at September 30, 2011:

| Year Issued                     | Classification | Number of<br>Warrants | Exercise<br>Price | Date of Expiration   |
|---------------------------------|----------------|-----------------------|-------------------|----------------------|
| 2010                            | Derivative     | 15,600,000            | \$ 1.40           | 10/26/2015-12/3/2015 |
| 2010                            | Derivative     | 3,200,000             | 1.00              | 9/26/2015-12/3/2015  |
| 2011                            | Equity         | 16,071                | 1.40              | 6/17/2018            |
| Total                           |                | 18,816,071            |                   |                      |
| Weighted average exercise price |                |                       | \$ 1.33           |                      |
| Weighted average life in years  |                |                       |                   | 4.0                  |



Table of Contents

**INVIVO THERAPEUTICS HOLDINGS CORP.**

[        ] Shares of Common Stock

Warrants to Purchase Up to [        ] Shares of Common Stock

and

[        ] Shares of Common Stock Underlying Warrants

**PROSPECTUS**

, 2011

**Table of Contents****PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution**

The following table sets forth the costs and expenses payable by us in connection with the sale of the securities being registered. All such costs and expenses shall be borne by us. All amounts are estimates except the fees payable to the SEC.

|                              |           |
|------------------------------|-----------|
| SEC Registration Fee         | \$ 1,146  |
| FINRA filing fee             |           |
| Printing and Edgar Filing    |           |
| Accounting Fees and Expenses |           |
| Legal Fees and Expenses      |           |
| Miscellaneous                |           |
| <b>Total</b>                 | <b>\$</b> |

**Item 14. Indemnification of Directors and Officers**

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

Under NRS Section 78.751, advances for expenses may be made by agreement if the director or officer affirms in writing that he has met the standards for indemnification and will personally repay the expenses if it is determined that such officer or director did not meet those standards.

Our bylaws include an indemnification provision under which we have the power to indemnify our directors, officers, former directors and officers, employees and other agents (including heirs and personal representatives) against all costs, charges and expenses actually and reasonably incurred, including an amount paid to settle an action or satisfy a judgment to which a director or officer is made a party by reason of being or having been a director or officer of the Company. Our bylaws further provide for the advancement of all expenses incurred in connection with a proceeding upon receipt of an undertaking by or on behalf of such person to repay such amounts if it is determined that the party is not entitled to be indemnified under our bylaws. No advance will be made by the Company to a party if it is determined that the party acted in bad faith. These indemnification rights are contractual, and as such will continue as to a person who has ceased to be a director, officer, employee or other agent, and will inure to the benefit of the heirs, executors and administrators of such a person.

Our bylaws do not eliminate or limit the liability of a director for: (i) an act or omission which involves intentional misconduct, fraud or a knowing violation of law; or (ii) the payment of dividends in violation of NRS 78.300.

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

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

---

**Table of Contents**

**Item 15. Recent Sales of Unregistered Securities**

Between November 2006 and June 2008, Messrs. Reynolds, Langer and Teng were issued 1,100,000, 600,000 and 100,000 shares of InVivo's common stock, respectively. These shares converted into 15,147,660 shares, 8,262,360 shares and 1,377,060 shares of our Common Stock, respectively, upon the closing of the Merger. Between August 2006 and the date of this registration statement, InVivo sold \$4,181,000 of principal amount of convertible notes (the Convertible Notes) to 54 accredited investors and 79,536 shares of its common stock to one investor for \$1,000,000. The Convertible Notes were converted into 379,989 shares of InVivo common stock before the closing of the Merger. The 79,536 shares issued to the Investor converted into 1,095,259 Shares of our Common Stock and the 379,989 shares issuable to the Convertible Note holders converted into 5,232,677 Shares of our Common Stock upon the closing of the Merger.

In October 2010, we issued 500,000 shares of our Common Stock for legal services to InVivo's counsel, Meister Seelig & Fein LLP at the closing of the Merger.

In September 2010, InVivo sold \$500,000 of principal amount of bridge notes and bridge warrants. \$150,000 of principal amount of the bridge notes and bridge warrants were purchased by an affiliate of Spencer Trask. Principal and accrued interest on the bridge notes converted into and was used to acquire units in the 2010 Private Placement and upon the closing of the Merger, the bridge warrants were exchanged for 500,000 New Bridge Warrants to acquire 500,000 shares of our Common Stock at a price of \$1.00 per share. As consideration for locating investors to participate in the bridge financing, Spencer Trask received warrants from InVivo that were exchanged on the closing of the Merger for New Bridge Warrants to purchase 100,000 shares of Common Stock at a price of \$1.00 per share. Spencer Trask received, upon conversion of the bridge notes, compensation in the same amount as it received for other units sold in the 2010 Private Placement.

In October, November and December 2010, we completed a private placement of 13 million units of our securities (consisting of shares of Common Stock and warrants to purchase Common Stock) and raised total gross proceeds of \$13 million and total net proceeds of \$10,913,954. We issued 13 million shares and 13 million warrants exercisable at \$1.40 to investors in the private placement. We paid Spencer Trask, as placement agent, a cash commission of 10% of the funds raised from the private placement. In addition, Spencer Trask received a non-accountable expense allowance equal to 3% of the proceeds raised in the private placement as well as warrants to purchase a number of shares of Common Stock equal to 20% of the Common Stock and 20% of the Common Stock underlying the Investor Warrants sold in the private placement. Spencer Trask was paid total cash consideration of \$1,690,000 and was issued warrants to purchase 2,600,000 shares of Common Stock at an exercise price of \$1.00 per share and warrants to purchase 2,600,000 shares of Common Stock at an exercise price of \$1.40 per share.

The transactions described above were exempt from registration under Section 4(2) of the Securities Act and Rule 506 of Regulation D thereunder, as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of these securities. The securities were offered only to accredited investors as defined under Rule 501(a) of Regulation D. Neither the Company nor any person acting on its behalf offered or sold these securities by any form of general solicitation or general advertising.

On February 14, 2011, we issued 27,541 shares of our Common Stock to George Calapai upon his exercise of stock options under our 2007 Stock Option Plan at an exercise price of \$0.0723 per share. The issuance of these shares was effected without registration in reliance on Section 4(2) of the Securities Act of 1933, as amended, as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of these shares.

On June 17, 2011, we issued a warrant for the purchase of 16,071 shares of Common Stock to Square 1 Bank. The warrant has a seven year term and is exercisable at \$1.40 per share. The issuance of this warrant was effected without registration in reliance on Section 4(2) of the Securities Act of 1933, as amended, as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of this warrant.

**Table of Contents**

On June 27, 2011, we issued 65,000 shares of Common Stock to CorProminence, LLC. The issuance of these shares was effected without registration in reliance on Section 4(2) of the Securities Act of 1933, as amended, as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of these shares.

On August 5, 2011, we issued 150,000 shares of Common Stock to Crystal Research Associates, LLC. The issuance of these shares was effected without registration in reliance on Section 4(2) of the Securities Act of 1933, as amended, as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of these shares.

On November 30, 2011, we issued 250,000 shares of Common Stock to John Derby in connection with his exercise of a warrant to purchase common stock previously issued. The exercise price paid upon exercise of the warrant was \$1.40 per share for a total of \$350,000.00, which has been received by us. The issuance of these securities was effected without registration in reliance on Section 4(2) of the Securities Act as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of such securities.

On November 30, 2011, we issued 50,267 shares of Common Stock to Andrew Meade in connection with his exercise of a warrant to purchase common stock previously issued. The exercise price paid upon exercise of the warrant was \$1.40 per share for a total of \$70,373.80, which has been received by us. The issuance of these securities was effected without registration in reliance on Section 4(2) of the Securities Act as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of such securities.

On November 30, 2011, we issued 50,000 shares of Common Stock to Andrew Meade in connection with his exercise of a warrant to purchase common stock previously issued. The exercise price paid upon exercise of the warrant was \$1.00 per share for a total of \$50,000.00, which has been received by us. The issuance of these securities was effected without registration in reliance on Section 4(2) of the Securities Act as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of such securities.

On November 30, 2011, we issued 10,000 shares of Common Stock to Fairfield Investment in connection with its exercise of a warrant to purchase common stock previously issued. The exercise price paid upon exercise of the warrant was \$1.40 per share for a total of \$14,000.00, which has been received by us. The issuance of these securities was effected without registration in reliance on Section 4(2) of the Securities Act as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of such securities.

On November 30, 2011, we issued 7,253 shares of Common Stock to Steve Nicholson in connection with his exercise of a warrant to purchase common stock previously issued. Mr. Nicholson paid the exercise price via the net issuance (i.e., cashless exercise) provision set forth in the warrant. The issuance of these securities was effected without registration in reliance on Section 4(2) of the Securities Act as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of such securities.

On December 1, 2011, we issued 300,000 shares of Common Stock to Mark Tompkins in connection with his exercise of a warrant to purchase common stock previously issued. The exercise price paid upon exercise of the warrant was \$1.40 per share for a total of \$420,000.00, which has been received by us. The issuance of these securities was effected without registration in reliance on Section 4(2) of the Securities Act as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of such securities.

On December 6, 2011, we issued 25,000 shares of Common Stock to Reiner Fenske in connection with his exercise of a warrant to purchase common stock previously issued. The exercise price paid upon exercise of the warrant was \$1.40 per share for a total of \$35,000.00, which has been received by us. The issuance of these securities was effected without registration in reliance on Section 4(2) of the Securities Act as a sale by the Company not involving a public offering. No underwriters were involved with the issuance of such securities.

**Table of Contents**

**Item 16. Exhibits and Financial Statement Schedules**

- 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 2.2 to the Company's Amendment No. 1 to Form S-1 Registration Statement (File No. 333-171998)).
- 2.3 Certificate of Merger (incorporated by reference from Exhibit 2.3 to the Company's Amendment No. 1 to Form S-1 Registration Statement (File No. 333-171998)).
- 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).
- 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.)
- 5.1 Opinion of BRL Law Group LLC\*\*
- 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 Amendment No. 1 to Form S-1 Registration Statement (File No. 333-171998)).
- 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 Form S-1 Registration Statement (File No. 333-171998)).



**Table of Contents**

|           |  |
|-----------|--|
| 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 Amendment No. 1 to Form S-1 Registration Statement (File No. 333-171998)).                            |
| 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 Amendment No. 1 to Form S-1 Registration Statement (File No. 333-171998)). |
| 10.7      | 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).                               |
| 10.8      | 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 filed 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).                      |
| 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).                 |
| 10.14     | License Agreement dated July 2007 between InVivo Therapeutics Corp. and Children's Medical Center Corporation (incorporated by reference from Exhibit 10.1 to the Company's Amendment No. 2 to Quarterly Report on Form 10-Q/A for the fiscal quarter ended March 31, 2011).                                     |
| 10.15     | 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 Company's Amendment No. 4 to Form S-1 Registration Statement (File No. 333-171998)).                   |

**Table of Contents**

|       |   |
|-------|---|
| 10.16 | Form of Scientific Advisory Board Agreement entered into by InVivo Therapeutics Corp. (incorporated by reference from Exhibit 10.13 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).  |
| 10.17 | 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 Form S-1 Registration Statement (File No. 333-171998)).          |
| 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).  |
| 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 filed on October 14, 2011).  |
| 10.25 | Lease Agreement, dated November 29, 2011, between InVivo Therapeutics Corporation and RB Kendall Fee, LLC.*   |
| 10.26 | Lease Guaranty, dated November 30, 2011, by InVivo Therapeutics Holdings Corporation.*  |
| 16    | Letter regarding change in certifying accountant (incorporated by reference from Exhibit 16 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).  |
| 21.1  | 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. *   |
| 23.2  | Consent of BRL Law Group LLC (included in Exhibit 5.1).   |
| 24.1  | Power of Attorney (included on signature page).*  |

\* Filed herewith

\*\* To be filed by amendment.

## **Table of Contents**

### **Item 17. Undertakings**

The undersigned registrant hereby undertakes:

1. To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
  - i. To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;
  - ii. To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement.
  - iii. To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;
2. That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
3. To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
4. That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:
  - i. If the registrant is relying on Rule 430B:
    - A. Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
    - B. Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date; or
  - ii. If the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the

## **Table of Contents**

registration statement as of the date it is first used after effectiveness. *Provided, however,* that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

5. That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities: The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- i. Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
- ii. Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
- iii. The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
- iv. Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

6. Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

7. (i) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b) (1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(ii) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cambridge, Commonwealth of Massachusetts, on December 15, 2011.

**INVIVO THERAPEUTICS HOLDINGS CORP.**

By: /s/ Frank M. Reynolds  
 Name: Frank M. Reynolds  
 Title: Chief Executive Officer and Chief Financial Officer (Principal Executive, Financial and Accounting Officer)

**POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS, each of the undersigned officers and directors of InVivo Therapeutics Holdings Corp. hereby severally constitutes Frank M. Reynolds with full power of substitution, his or her true and lawful attorney with full power to him, to sign for the undersigned and in his or her name in the capacity indicated below, the registration statement filed herewith and any and all amendments to said registration statement (including amendments pursuant to Rule 462), and generally to do all such things in his or her name and in his or her capacity as an officer or director to enable InVivo Therapeutics Holdings Corp. to comply with the provisions of the Securities Act of 1933, and all requirements of the Securities and Exchange Commission, hereby ratifying and confirming his or her signature as it may be signed by his or her said attorney to said registration statement and any and all amendments thereto.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

| Signature              | Title   | Date              |
|------------------------|---|-------------------|
| /s/ Frank M. Reynolds  |   | December 15, 2011 |
| Frank M. Reynolds      | Chairman, Chief Executive Officer and Chief Financial Officer (Principal Executive, Financial and Accounting Officer) | December 12, 2011 |
| /s/ Richard J. Roberts | Director  |                   |
| Richard J. Roberts     |   | December 13, 2011 |
| /s/ George Nolen       | Director  |                   |
| George Nolen           | Director  | December 15, 2011 |
| /s/ Christi M. Pedra   |   |                   |

Christi M. Pedra

December 15, 2011

/s/ Adam K. Stern

Director

Adam K. Stern

II-9

**Table of Contents**

**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 2.2 to the Company's Amendment No. 1 to Form S-1 Registration Statement (File No. 333-171998)).
- 2.3 Certificate of Merger (incorporated by reference from Exhibit 2.3 to the Company's Amendment No. 1 to Form S-1 Registration Statement (File No. 333-171998)).
- 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).
- 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.)
- 5.1 Opinion of BRL Law Group LLC\*\*
- 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 Amendment No. 1 to Form S-1 Registration Statement (File No. 333-171998)).
- 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 Form S-1 Registration Statement (File No. 333-171998)).

**Table of Contents**

|           |  |
|-----------|--|
| 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 Amendment No. 1 to Form S-1 Registration Statement (File No. 333-171998)).                            |
| 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 Amendment No. 1 to Form S-1 Registration Statement (File No. 333-171998)). |
| 10.7      | 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).                               |
| 10.8      | 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 filed 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).                      |
| 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).                 |
| 10.14     | License Agreement dated July 2007 between InVivo Therapeutics Corp. and Children's Medical Center Corporation (incorporated by reference from Exhibit 10.1 to the Company's Amendment No. 2 to Quarterly Report on Form 10-Q/A for the fiscal quarter ended March 31, 2011)                                      |



**Table of Contents**

|       |  |
|-------|--|
| 10.15 | 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 Company’s Amendment No. 4 to Form S-1 Registration Statement (File No. 333-171998)). |
| 10.16 | Form of Scientific Advisory Board Agreement entered into by InVivo Therapeutics Corp. (incorporated by reference from Exhibit 10.13 to the Company’s Current Report on Form 8-K, as filed with the SEC on November 1, 2010).   |
| 10.17 | 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 Form S-1 Registration Statement (File No. 333-171998)).                               |
| 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).   |
| 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 filed on October 14, 2011).   |
| 10.25 | Lease Agreement, dated November 29, 2011, between InVivo Therapeutics Corporation and RB Kendall Fee, LLC.*  |
| 10.26 | Lease Guaranty, dated November 30, 2011, by InVivo Therapeutics Holdings Corporation.*   |
| 16    | Letter regarding change in certifying accountant (incorporated by reference from Exhibit 16 to the Company’s Current Report on Form 8-K, as filed with the SEC on November 1, 2010).   |
| 21.1  | 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.*   |
| 23.2  | Consent of BRL Law Group LLC (included in Exhibit 5.1).  |
| 24.1  | Power of Attorney (included on signature page).*   |

\* Filed herewith

\*\* To be filed by amendment