INVIVO THERAPEUTICS HOLDINGS CORP.
Form S-3/A
January 09, 2012
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As filed with the Securities and Exchange Commission on January 9, 2012.

Registration Statement No. 333-178584

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

PRE-EFFECTIVE AMENDMENT NO. 1

TO FORM S-1

ON

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

INVIVO THERAPEUTICS HOLDINGS CORP.

(Exact name of registrant as specified in its charter)

Nevada	36-4528166
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

One Broadway, 14th Floor

Cambridge, Massachusetts 02142

(617) 475-1520

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Francis M. Reynolds

Chief Executive Officer

InVivo Therapeutics Holdings Corp.

One Broadway, 14th Floor

Cambridge, Massachusetts 02142

(617) 475-1520

(Name, address, including zip code, and telephone number, including area code, of agent for service)

With copies to:

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Approximate date of commencement of proposed sale to public: From time to time after this Registration Statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

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, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please 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 registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ¨

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ¨

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 definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered (1)	Proposed Maximum Offering Price Per Unit	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee (2)
Common Stock, $0.01 par value per share		(3)	(3)	
Warrants		(3)	(3)	
Units (4)		(3)	(3)	
Total	$50,000,000		$50,000,000	$5,730.00

(1) There are being registered under this registration statement such indeterminate number of shares of common stock; such indeterminate number of warrants to purchase common stock and/or units; and such indeterminate number of units as may be sold by the registrant from time to time, which together shall have an aggregate initial offering price not to exceed $50,000,000. Any securities registered hereunder

may be sold separately or as units with other securities registered hereunder. The securities registered hereunder also include such indeterminate number of shares of common stock as may be issuable upon exercise of warrants or pursuant to the anti-dilution provisions of such warrants. In addition, pursuant to Rule 416 under the Securities Act of 1933, as amended (the Securities Act), the shares being registered hereunder include such indeterminate number of shares of common stock as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends, or similar transactions.

(2) Calculated pursuant to Rule 457(o) under the Securities Act. An additional $40,000,000 of securities are being registered pursuant to this Amendment No. 1 to Form S-1 on Form S-3, resulting in an additional registration fee of $4,584. Of the total registration fee, $1,146 was previously paid in connection with the initial filing of this Registration Statement on Form S-1 (File No. 333-178584), which was filed by the registrant on December 16, 2011.

(3) Not required to be included in accordance with General Instruction II.D. of Form S-3.

(4) Each unit will represent an interest in common stock and warrants, which may or may not be separable from one another.

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, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), shall determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities 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 January 9, 2012

PROSPECTUS

INVIVO THERAPEUTICS HOLDINGS CORP.

$50,000,000

Common Stock

Warrants

Units

This prospectus relates to common stock, warrants and units that we may sell from time to time in one or more offerings up to a total dollar amount of $50,000,000 on terms to be determined at the time of sale. We will provide specific terms of these securities in supplements to this prospectus. You should read this prospectus and any supplement carefully before you invest. This prospectus may not be used to offer and sell securities unless accompanied by a prospectus supplement for those securities.

Our common stock is quoted on the OTC Bulletin Board under the symbol NVIV.OB. On January 5, 2012, the last sales price of our common stock as reported on the OTC Bulletin Board was $2.58 per share.

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

Investing in our securities involves a high degree of risk. Beginning on page 4, we discuss several Risk Factors that you should consider before investing in our securities.

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

The date of this prospectus is , 2012.

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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.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, using a shelf registration process. Under this shelf registration process, we may sell any combination of the securities described in this prospectus in one or more offerings up to a total dollar amount of $50,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the securities being offered and the terms of that offering. The prospectus supplement may also add to, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with the additional information described under the heading Where You Can Find More Information carefully before making an investment decision.

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

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

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

ABOUT INVIVO THERAPEUTICS HOLDINGS CORP.

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.), a publicly traded company incorporated under the laws of the State of Nevada. InVivo became a wholly owned subsidiary of InVivo Therapeutics, which continues to operate the business of InVivo. As part of the Merger, InVivo Therapeutics 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 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 InVivo Therapeutics accompanied by a recapitalization. At the date of the Merger, the 6,999,981 outstanding InVivo Therapeutics shares are

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reflected as an issuance of InVivo common stock to the prior shareholders of InVivo Therapeutics. InVivo Therapeutics 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, InVivo Therapeutics 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 InVivo Therapeutics 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 InVivo Therapeutics were transferred to the Split-Off Shareholders in the Split-Off. InVivo Therapeutics executed a split off agreement with the Split-Off Shareholders which obligates the Split-Off Shareholders to assume all prior liabilities associated with InVivo Therapeutics 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. Prior to the Merger, InVivo had completed a bridge financing, wherein it sold $500,000 in principal amount of its bridge notes and 36,310 bridge warrants to accredited investors. On December 21, 2011, we completed a private placement of 980,382 shares of Common Stock and sold a warrant to purchase 343,137 shares of Common Stock to one accredited investor.

Our principal executive offices are located at One Broadway, 14th Floor, Cambridge, Massachusetts 02142. 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.

Business Overview

We develop and commercialize new technologies for the treatment of spinal cord injuries. Our proprietary technology was co-invented by Robert S. Langer, ScD, Professor at Massachusetts Institute of Technology, 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.

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

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

A biocompatible hydrogel for local controlled release of methylprednisolone to treat acute spinal cord injuries and peripheral nerve injuries.

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

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.

Our first product, the biocompatible polymer scaffolding device to treat acute spinal cord injuries is expected to be regulated by the FDA as a Class III medical device. A Class III medical device will require FDA approval of a Pre-Market Approval Application (PMA) before we can start selling the product in the U.S. We will be required to demonstrate safety and efficacy in human clinical studies before we can submit a PMA to the FDA. Before clinical studies can commence, we must submit an Investigational Device Exemption application (IDE) to the FDA and the FDA must approve the IDE. 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 application for our biopolymer scaffolding device to the FDA on July 7, 2011. The FDA has provided us with comments to the IDE filing and we are in the process of responding to the FDA comments. We anticipate that the IDE will be approved by the FDA during 2012. We plan to first conduct a pilot study in ten acute spinal cord patients followed by a larger pivotal study. The completion of the human clinical studies and the FDA approval of the PMA could take between three to five years to achieve, depending on a number of factors including the FDA review and clearance process for the IDE, the clinical trial designs and amount of time it will take to enroll and treat patients, and the FDA review and approval process for the PMA. The FDA regulatory approval process is lengthy, and the outcome is highly uncertain. The risk exists that the first product may never be approved, or that the approval is significantly delayed such that we are unable to raise additional capital to continue to fund the Company. Please see Risk Factors beginning on page 4 for a more detailed discussion of these risks.

If the product is approved by the FDA, we will need to expand manufacturing capacity, and establish sales, marketing and distribution channels to sell the product. We intend to retain manufacturing rights and plans to market and sell the product through a direct sales force in the United States. For major markets outside the United States, we plan to seek regulatory approvals after the clinical trials are conducted in the United States.

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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 a number of animal studies, including a third primate study which began in 2011. 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. Initial results are consistent with data from prior monkey and rodent 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.

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

Our principal executive offices are located at One Broadway, 14th Floor, Cambridge, Massachusetts 02142. Our telephone number is (617) 475-1520. We maintain a website at *www.invivotherapeutics.com*. The URL of our website is included herein as an inactive textual reference. Information contained on, or accessible through, our website is not a part of, and is not incorporated by reference into, this prospectus or any prospectus supplement.

RISK FACTORS

Investing in our securities involves significant risks. Before making an investment decision, you should carefully consider these risks as well as other information we include or incorporate by reference in this prospectus and any prospectus supplement. The risks and uncertainties we have described are not the only ones facing our company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business operations.

Risks Relating to Our Business and Our Industry

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

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

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

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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. Our existing current capital resources will fund operations through June 30, 2012 and we will need to raise substantial capital to develop our products and fund future operations. Our future capital requirements will depend on many factors, including:

- the progress and costs of our research and development programs, including our ability to develop our current portfolio of therapeutic products, or discover and develop new ones;
- our ability, or our partners ability and willingness, to advance partnered products or programs;
- the cost of prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the progress, scope, costs, and results of our preclinical and clinical testing of any current or future products;
- the time and cost involved in obtaining regulatory approvals;
- the cost of manufacturing our product candidates;
- expenses related to complying with Good Manufacturing Practice manufacturing of product candidates;
- costs of financing the purchases of additional capital equipment and development technologies;
- competing technological and market developments;
- our ability to establish and maintain collaborative and other arrangements with third parties to assist in bringing our products to market and the cost of such arrangements;
- the amount and timing of payments or equity investments that we receive from collaborators and the timing and amount of expenses we incur;

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costs associated with the integration of any new operation, including costs relating to future mergers and acquisitions with companies that have complementary capabilities;

expenses related to the establishment of sales and marketing capabilities for products awaiting approval or products that have been approved;

the level of our sales and marketing expenses; and

our ability to introduce and sell new products.

We cannot assure you that we will not need additional capital sooner than currently anticipated. We will need to raise substantial additional capital to fund our future operations. We cannot be certain that additional financing will be available on acceptable terms, or at all. In recent years, it has been difficult for companies to raise capital due to a variety of factors, which may or may not continue. If we are not successful in raising additional capital, we may not be able to continue as a going concern. To the extent we raise additional capital through the sale of equity securities, the ownership position of our existing stockholders could be substantially diluted. If additional funds are raised through the issuance of preferred stock or debt securities, these securities are likely to have rights, preferences and privileges senior to our common stock. Fluctuating interest rates could also increase the costs of any debt financing we may obtain.

Our products will represent new and rapidly evolving technologies.

Our proprietary spinal cord injury treatment technology depends on new, rapidly evolving technologies and on the marketability and profitability of our products. Approval by applicable regulatory agencies and commercialization of our spinal cord injury treatment technology could fail for a variety of reasons, both within and outside of our control. Furthermore, because there are no approved treatments for spinal cord injuries, the regulatory requirements governing this type of product may be more rigorous or less clearly established than for other analogous products.

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

We license patents and core intellectual property from CMCC and MIT under the CMCC license. The CMCC license agreement imposes certain payment, milestone achievement, reporting, confidentiality and other obligations on us. In the event that we were to breach any of the obligations and fail to cure, CMCC would have the right to terminate the CMCC license agreement upon notice. In addition, CMCC has the right to terminate the CMCC license agreement upon the bankruptcy or receivership of the Company. The termination of the CMCC license would have a material adverse effect on our business, as all of our current product candidates are based on the patents and licensed intellectual property. If any dispute arises with respect to our arrangement with CMCC or MIT, such dispute may disrupt our operations and would likely have a material and adverse impact on us if resolved in a manner that is unfavorable to us.

We will face substantial competition.

The biotechnology industry in general is subject to intense competition and rapid and significant technological change. We have many potential competitors, including major drug companies, specialized biotechnology firms, academic institutions, government agencies and private and public research institutions. Many of these competitors have significantly greater financial and technical resources than us, and superior experience and expertise in research and development, preclinical testing, designing and implementing clinical trials, regulatory processes and approvals, production and manufacturing, and sales and marketing of approved products.

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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, which could affect the cost of such clinical trials. Safety concerns may

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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.

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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.

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Even if we establish new collaborations, these relationships may never result in the successful development or commercialization of any product candidates for several reasons both within and outside of our control.

We will require quantities of manufactured product and may require third party manufacturers to fulfill some of our inventory requirements.

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

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

We may rely on third-party suppliers and vendors for some of the materials used in the manufacture of our products or other of our product candidates. Any significant problem experienced by one of our suppliers could result in a delay or interruption in the supply of materials to us until such supplier resolves the problem or an alternative source of supply is located. Any delay or interruption could negatively affect our operations.

We will rely upon third parties for laboratory testing, animal and human studies.

We have been and will continue to be dependent on third-party contract research organizations to conduct some of our laboratory testing, animal and human studies. If we are unable to obtain any necessary testing services on acceptable terms, we may not complete our product development efforts in a timely manner. If we rely on third parties for laboratory testing and/or animal and human studies, we may lose some control over these activities and become too dependent upon these parties. These third parties may not complete testing activities on schedule or when we request. We may not be able to secure and maintain suitable contract research organizations to conduct our laboratory testing and/or animal and human studies. We are responsible for confirming that each of our clinical trials is conducted in accordance with our general plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good 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.

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

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

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

We may have product liability exposure.

We will have exposure to claims for product liability. Product liability coverage is expensive and sometimes difficult to obtain. We may not be able to obtain or maintain insurance at a reasonable cost. There can be no assurance that existing insurance coverage will extend to other products in the future. Any product liability insurance coverage may not be sufficient to satisfy all liabilities resulting from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable items, if at all. Even if a claim is not successful, defending such a claim would be time-consuming and expensive, may damage our reputation in the marketplace, and would likely divert management s attention.

Our products are new and will require market acceptance.

Even if we receive regulatory approvals for the commercial sale of our product candidates, the commercial success of these product candidates will depend on, among other things, their acceptance by physicians, patients, third party payers such as health insurance companies and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. If our product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, both within and outside of our control. If our product candidates do not become widely accepted by physicians, patients, third party payers and other members of the medical community, our business, financial condition and results of operations would be materially and adversely affected.

Physicians and hospitals will require training in order to utilize our products.

Our products have not been utilized in the past for spinal cord injury treatment. As is typical in the case of a new and rapidly evolving technology or medical treatment, demand and market acceptance for recently 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.

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

Our successes may depend, in part, on the extent to which reimbursement for the costs of therapeutic products and related treatments will be available from third-party payers such as government health administration authorities, private health insurers, managed care programs, and other organizations. Over the past decade, the cost of health care has risen significantly, and there have been numerous proposals by legislators, regulators, and third-party health care payers to curb these costs. Some of these proposals have involved limitations on the amount of reimbursement for certain products. Similar federal or state health care legislation may be adopted in the future and any products that we or our collaborators seek to commercialize may not be considered cost-effective. Adequate third-party insurance coverage may not be available for us to establish and maintain price levels that are sufficient for us to continue our business or for realization of an appropriate return on investment in product development.

We will be subject to environmental, health and safety laws.

We are subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and humans, emissions and wastewater discharges, and the use and disposal of hazardous or potentially hazardous substances used in connection with our research, including infectious disease agents. We also cannot accurately predict the extent of regulations that might result from any future legislative or administrative action. Any of these laws or regulations could cause us to incur additional expense or restrict our operations. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

We must maintain the proprietary nature of our products and must operate without infringing on the proprietary rights of others.

Our success in large part depends on our ability to maintain the proprietary nature of our licensed technology. We will rely on a combination of patent, trademark, copyright and trade secret laws, as well as confidentiality agreements, license agreements and technical measures to protect our proprietary rights. We and our licensors must prosecute and maintain existing patents and obtain new patents. Some of our proprietary information may not be patentable, and there can be no assurance that others will not utilize similar or superior solutions to compete with us. We cannot guarantee that we will develop proprietary products and services or processes that are patentable, and that if issued, any patent will give a competitive advantage or that such patent will not be challenged by third parties, or that the patents of others will not have a material adverse effect on our ability to do business. We intend to register certain trademarks in, or claim certain trademark rights in, the United States and/or foreign jurisdictions. We cannot assure you that our means of protecting our proprietary rights will suffice or that our competitors will not independently develop competitive technology or duplicate processes or design around patents or other intellectual property rights issued to us.

We also must operate without infringing the proprietary rights of third parties or allowing third parties to infringe our rights. Our research, development and commercialization activities, including any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents owned by third parties and to which we do not hold licenses or other rights. There may be rights that we are not aware of, including applications that have been filed but not published that, when issued, could be asserted against us. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or biologic treatment candidate that is the subject of the suit.

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our trade secrets or other confidential information could be compromised by disclosure during this type of litigation.

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

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

We are dependent on our management and other key personnel.

We depend on our senior executive officers as well as key scientific and other personnel. The loss of any of these individuals could harm our business and significantly delay or prevent the achievement of research, development or business objectives. Competition for qualified employees is intense among biotechnology companies, and the loss of qualified employees, or an inability to attract, retain and motivate additional highly skilled employees could hinder our ability to successfully develop marketable products.

Our future success also depends on our ability to identify, attract, hire, train, retain and motivate other highly skilled scientific, technical, marketing, managerial and financial personnel. Although we will seek to hire and retain qualified personnel with experience and abilities commensurate with our needs, there is no assurance that we will succeed despite our collective efforts. The loss of the services of any of the principal members of our management or other key personnel could hinder our ability to fulfill our business plan and further develop and commercialize our products and services. Competition for personnel is intense, and any failure to attract and retain the necessary technical, marketing, managerial and financial personnel would have a material adverse effect on our business, prospects, financial condition and results of operations. Although we presently do not maintain key person life insurance policies on any of our personnel, we are currently in the process of obtaining key man insurance on Frank Reynolds, our Chairman, Chief Executive Officer and Chief Financial Officer.

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Risks Related to Investment in Our Securities

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

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

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

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

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

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

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

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

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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 us, there can be no assurance that we will not be liable for any or all of such liabilities. Any such liabilities that survive the Split-Off could harm our revenues, business, prospects, financial condition and results of operations upon our acceptance of responsibility for such liabilities.

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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.

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

In the future, we may issue additional authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of our present stockholders. We may also issue additional shares of our common stock or other securities that are convertible into or exercisable for common stock in connection with hiring or retaining employees, future acquisitions, future sales of our securities for capital raising purposes, or for other business purposes. The future issuance of any such additional shares of common stock may create downward pressure on the trading price of the common stock. There can be no assurance that we will not be required to issue additional shares, warrants or other convertible securities in the future in conjunction with any capital raising efforts, including at a price (or exercise prices) below the price at which shares of our common stock are currently traded on the OTC Bulletin Board.

Our common stock is controlled by insiders.

Our officers and directors beneficially own approximately 34% 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.

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

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

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

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

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

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

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

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

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WHERE YOU CAN FIND MORE INFORMATION

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

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

Our Internet address is *www.invivotherapeutics.com*. The information on our Internet website is not incorporated by reference in this prospectus or any prospectus supplement.

SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION

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

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to incorporate into this prospectus information and reports that we file with the SEC. This means that we can disclose important information to you by referring to other documents that contain that information. Any information that we incorporate by reference is considered part of this prospectus. The documents and reports that we list below are incorporated by reference into this prospectus, other than any portion of any such documents that are not deemed filed under the Exchange Act in accordance with the Exchange Act and applicable SEC rules. In addition, all documents and reports which we file pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus and prior to the termination of the offering made hereby are incorporated by reference in this prospectus as of the respective filing dates of these documents and reports. Statements contained in

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documents that we file with the SEC and that are incorporated by reference in this prospectus will automatically update and supersede information contained in this prospectus, including information in previously filed documents or reports that have been incorporated by reference in this prospectus, to the extent the new information differs from or is inconsistent with the old information.

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

(1) Our Annual Report on Form 10-K for the fiscal year ended December 31, 2010, filed on March 24, 2011, as amended by Amendment No. 1 filed on April 29, 2011, Amendment No. 2 filed on June 30, 2011, and Amendment No. 3 filed on July 18, 2011;

(2) Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, filed on May 16, 2011, as amended by Amendment No. 1 filed on June 30, 2011 and Amendment No. 2 filed on July 18, 2011;

(3) Our Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, filed on August 10, 2011;

(4) Our Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, filed on November 14, 2011;

(5) Our Current Reports on Form 8-K filed on March 15, March 17, April 29, May 31, June 7, June 30, July 8, August 4, October 4, October 14 and December 22, 2011;

(6) All of our filings pursuant to the Exchange Act after the date of filing the initial registration statement and prior to the effectiveness of the registration statement; and

(7) The description of our common stock contained in our Registration Statement on Form 8-A filed on June 30, 2006, including any amendments or reports filed for the purpose of updating such description.

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

InVivo Therapeutics Holdings Corp.

One Broadway, 14th Floor

Cambridge, Massachusetts 02142

Attn: Investor Relations

(617) 475-1520

Any statement contained in a document that is incorporated by reference will be modified or superseded for all purposes to the extent that a statement contained in this prospectus or any prospectus supplement, or in any other document that is subsequently filed with the SEC and incorporated by reference, modifies or is contrary to that previous statement. Any statement so modified or superseded will not be deemed to be a part of this prospectus or any prospectus supplement, except as so modified or superseded. Because information that we later file with the SEC will update and supersede previously incorporated information, you should look at all of the SEC filings that we incorporate by reference to determine if any of the statements in this prospectus or any prospectus supplement or in any documents previously incorporated by reference have been modified or superseded.

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USE OF PROCEEDS

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

- the acquisition of other companies, businesses, products or technologies;
- the research, development and pre-clinical and clinical trials for our product candidates;
- the repayment and refinancing of debt;
- capital expenditures;
- working capital; and
- any other purpose that we may specify in any prospectus supplement.

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

THE SECURITIES WE MAY OFFER

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

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

- common stock;
- warrants to purchase common stock or units;
- units comprised of common stock and warrants; or
- any combination of the foregoing securities.

In this prospectus, we refer to the common stock, warrants and units collectively as securities. The total dollar amount of all securities that we may issue will not exceed $50,000,000.

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

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DESCRIPTION OF COMMON STOCK

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

Under our articles of incorporation, we have authority to issue 200,000,000 shares of common stock, par value $0.0001 per share. As of December 31, 2011, there were 53,760,461 shares of common stock issued and outstanding. All shares of common stock will, when issued, be duly authorized, fully paid and nonassessable. Accordingly, the full price for the outstanding shares of common stock will have been paid at issuance and any holder of our common stock will not be later required to pay us any additional money for such common stock.

In addition, as of December 31, 2011:

- there were outstanding warrants to purchase an aggregate of up to 18,405,975 shares of our common stock at a weighted average exercise price of $1.42 per share;
- there were an aggregate of 6,302,894 shares of our common stock subject to outstanding stock options at a weighted average exercise price of $0.76 per share; and
- 2,536,259 shares of our common stock were reserved for future issuances under our incentive compensation plans and 401(k) plan.

The holders of common stock are entitled to one vote per share on all matters submitted to a vote of the stockholders, including the election of directors. Generally, all matters to be voted on by stockholders must be approved by a majority (or, in the case of election of directors, by a plurality) of the votes entitled to be cast by all shares of common stock that are present in person or represented by proxy. Except as otherwise provided by law, amendments to the articles of incorporation generally must be approved by a majority of the votes entitled to be cast by all outstanding shares of common stock. Our articles of incorporation do not provide for cumulative voting in the election of directors. The holders of common stock will be entitled to such cash dividends as may be declared from time to time by the Board from funds available. The holders of common stock have no preferential or preemptive right and no subscription, redemption or conversion privileges with respect to the issuance of additional shares of our common stock. Upon liquidation, dissolution or winding up of the Company, the holders of common stock will be entitled to receive pro rata all assets available for distribution to such holders after payment of our liabilities.

Registrar and Transfer Agent

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

Trading Market

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

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DESCRIPTION OF WARRANTS

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

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

- the title of the warrants;
- the offering price and aggregate number of warrants offered;
- the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security;
- the date on and after which the warrants and the related securities will be separately transferable;
- any information with respect to book-entry procedures;
- in the case of warrants to purchase common stock or units, the number of shares of common stock or units, as the case may be, purchasable upon the exercise of one warrant and the price at which these securities may be purchased upon such exercise;
- the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement and the warrants;
- the terms of any rights to redeem or call the warrants;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
- the dates on which the right to exercise the warrants will commence and expire;
- the manner in which the warrant agreement and warrants may be modified;
- a discussion of any material U.S. federal income tax considerations of holding or exercising the warrants;

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

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

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DESCRIPTION OF UNITS

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

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

We will incorporate by reference into the registration statement of which this prospectus is a part the form of unit agreement, including a form of unit certificate, if any, that describes the terms of the series of units we are offering before the issuance of the related series of units. The following summaries of material provisions of the units and the unit agreements are subject to, and qualified in their entirety by reference to, all the provisions of the unit agreement applicable to a particular series of units. We urge you to read the applicable prospectus supplements related to the units that we sell under this prospectus, as well as the complete unit agreements that contain the terms of the units.

General

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

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

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any provisions of the governing unit agreement that differ from those described below; and
- any provisions for the issuance, payment, settlement, transfer, or exchange of the units or of the securities comprising the units.

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

Issuance in Series

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

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Enforceability of Rights by Holders of Units

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

Title

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

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

Anti-Takeover Effects of Provisions of Nevada State Law

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

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

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

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

Our amended and restated bylaws also provide that stockholders may only act at meetings of stockholders and not by written consent in lieu of a stockholders meeting. Our amended and restated bylaws provide that stockholders may not call a special meeting of stockholders. Rather, only the Chairman of our Board, the President or the Board of Directors pursuant to a resolution approved by a majority of the entire Board of Directors are able to call special meetings of stockholders. Our amended and restated bylaws also provide that stockholders may only conduct business at special meetings of stockholders that was specified in the notice of the meeting. These provisions may discourage another person or entity from making a tender offer, even if it acquired a majority of our outstanding voting stock, because the person or entity could only take action at a duly called stockholders meeting relating to the business specified in the notice of meeting and not by written consent.

Indemnification of Directors and Officers

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

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

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

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

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

PLAN OF DISTRIBUTION

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

- directly to investors;
- through agents to the public or to investors;
- directly to agents
- to one or more underwriters or dealers for resale to the public or to investors;
- in at the market offerings, within the meaning of Rule 415(a)(4) of the Securities Act, to or through a market maker or into an existing trading market, or an exchange or otherwise; or
- through a combination of any of these methods of sale.

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

- a fixed price or prices, which may be changed;
- market prices prevailing at the time of sale;
- prices related to prevailing market prices; or
- negotiated prices.

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

- the name or names of any agents or underwriters;
- the purchase price of our securities being offered and the proceeds we will receive from the sale;

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

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

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any public offering price;

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

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

Underwriters

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

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

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

Agents

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

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Direct Sales

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

Trading Markets and Listing of Securities

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

Stabilization Activities

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

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

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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.

LEGAL MATTERS

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

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INVIVO THERAPEUTICS HOLDINGS CORP.

$50,000,000

Common Stock

Warrants

Units

PROSPECTUS

, 2012

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 14. Other Expenses of Issuance and Distribution.

The expenses payable by the registrant in connection with the issuance and distribution of the securities being registered are set forth in the following table (all amounts except the registration fee are estimated):

SEC registration fee	$ 5,730
Legal fees and expenses	75,000
Accounting fees and expenses	5,000
Printing fees and expenses	10,000
Transfer agent fees and expenses	5,000
Miscellaneous expenses	5,000
Total	$ 105,730

Item 15. Indemnification of Directors and Officers.

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

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

Our bylaws include an indemnification provision under which we have the power to indemnify our directors, officers, former directors and officers, employees and other agents (including heirs and personal representatives) against all costs, charges and expenses actually and reasonably incurred, including an amount paid to settle an action or satisfy a judgment to which a director or officer is made a party by reason of being or having been a director or officer of the Company. Our bylaws further provide for the advancement of all expenses incurred in connection with a proceeding upon receipt of an undertaking by or on behalf of such person to repay such amounts unless it is determined that the party is entitled to be indemnified under our bylaws. No advance will be made by the Company to a party if it is determined that the party acted in bad faith. These indemnification rights are contractual, and as such will continue as to a person who has ceased to be a director, officer, employee or other agent, and will inure to the benefit of the heirs, executors and administrators of such a person. Our bylaws do not eliminate or limit the liability of a director for: (i) an act or omission which involves intentional misconduct, fraud or a knowing violation of law; or (ii) the payment of dividends in violation of NRS 78.300. These provisions may be sufficiently broad to indemnify such persons for liabilities arising under the Securities Act of 1933, as amended, in which case such provision is against public policy as expressed such Act and is therefore unenforceable.

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

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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.

Item 16. Exhibits.

The exhibits listed in the Exhibit Index immediately preceding the exhibits are filed as part of this registration statement on Form S-3.

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, as amended (the Securities Act);

(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 the 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; and

(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;

provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act), that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purposes of determining any liability under the Securities Act, 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 the 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.

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(4) That, for the purpose of determining liability under the Securities Act 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 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 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 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, such 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;

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(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) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant s annual report pursuant to Section 13(a) or 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan s annual report pursuant to Section 15(a) of the Exchange Act) that is incorporated by reference in the registration statement 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.

(7) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the indemnification provisions described herein, 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 Securities 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 Securities Act and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and 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 this 9th day of January, 2012.

INVIVO THERAPEUTICS HOLDINGS CORP.

By: /s/ Francis M. Reynolds
Francis M. Reynolds
Chief Executive Officer and Chief Financial Officer

We, the undersigned directors of InVivo Therapeutics Holdings Corp., hereby severally constitute and appoint Francis M. Reynolds our true and lawful attorney with full power to him to sign for us and in our names in the capacities indicated below the Registration Statement on Form S-3 filed herewith and any and all pre-effective and post-effective amendments to said Registration Statement and generally to do all such things in our name and behalf in our capacities as directors to enable InVivo Therapeutics Holdings Corp. to comply with the provisions of the Securities Act of 1933, as amended, and all requirements of the Securities and Exchange Commission, hereby ratifying and confirming our signatures as they may be signed by our said attorney to said Registration Statement and any and all amendments thereto.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Francis M. Reynolds **Francis M. Reynolds**	Chairman, Chief Executive Officer and Director (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	January 9, 2012
/s/ Richard J. Roberts **Richard J. Roberts**	Director	January 9, 2012
/s/ George Nolen **George Nolen**	Director	January 9, 2012
/s/ Christi M. Pedra **Christi M. Pedra**	Director	January 9, 2012
/s/ Adam K. Stern **Adam K. Stern**	Director	January 6, 2012

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EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION
**1.1	Form of Underwriting Agreement.
**4.1	Form of Common Stock Warrant Agreement.
**4.2	Form of Unit Agreement and Unit Certificate.
*5.1	Opinion of Greenberg Traurig, LLP, counsel to the Registrant.
*23.1	Consent of Wolf & Company, P.C.
*23.2	Consent of Greenberg Traurig, LLP (included in Exhibit 5.1).
*24.1	Power of Attorney (contained in signature page).

* Filed herewith.
** To be subsequently filed by amendment to this registration statement or by a report filed under the Securities Exchange Act of 1934, as amended, and incorporated or deemed to be incorporated by reference to this registration statement.