INVIVO THERAPEUTICS HOLDINGS CORP.
Form S-1/A
June 30, 2011
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As filed with the Securities and Exchange Commission on June 30, 2011

Registration No. 333-171998

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 3

to

FORM S-1

REGISTRATION STATEMENT

UNDER THE SECURITIES ACT OF 1933

INVIVO THERAPEUTICS HOLDINGS CORP.

(Exact Name of Registrant as Specified in Its Charter)

Nevada	**3841**	**36-4528166**
(State or other Jurisdiction of Incorporation or Organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

One Broadway, 14th Floor Cambridge, MA 02142 (617) 475-1520

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

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

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

Copies to:

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

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

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

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Share	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock, $.00001 par value per Share(1)	26,047,200	$0.93(2)	$24,223,896	$2,812*

(1) Pursuant to Rule 416 under the Securities Act, this registration statement also covers such indeterminate number of additional shares of common stock as may be issuable with respect to the shares being registered hereunder as a result of any stock splits, stock dividends or similar transactions.
(2) Estimated solely for the purpose of calculating the registration fee, and based on the average of the high and low prices of the Common Stock on June 28, 2011 as reported on the Over-the-Counter Bulletin Board operated by the National Association of Securities Dealers Inc. in accordance with Rules 457(c) and 457(h) under the Securities Act of 1933.
* Previously paid.

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

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

Subject to Completion, Dated June 30, 2011

26,047,200 Shares of Common Stock

INVIVO THERAPEUTICS HOLDINGS CORP.

This prospectus relates to the following offerings by certain of our stockholders and warrantholders, which we refer to as Selling Securityholders :

- the resale of up to 12,848,600 shares of common stock purchased in a private placement;
- the resale of up to 12,848,600 shares of common stock that are issuable on exercise of the investor warrants that were acquired in a private placement; and
- the resale of up to 350,000 shares of common stock that are issuable on exercise of the new bridge warrants that were issued to warrantholders in connection with our recent merger.

Holders of the investor warrants and new bridge warrants may currently purchase one share of common stock for each warrant exercised. The exercise price and number of shares of common stock issuable upon exercise of the warrants is subject to further adjustment in certain circumstances.

We will not receive any proceeds from the sale of these securities, although we will receive the exercise price for any warrants that are exercised. We are registering securities for resale by the Selling Securityholders, but that does not necessarily mean that they will sell any of the securities. Any securities sold by the Selling Securityholders will be offered at market or privately negotiated prices.

The investor warrants and the new bridge warrants are exercisable at $1.40 per warrant and $1.00 per warrant, respectively, at any time on or before the fifth anniversary of the date of issuance.

Our common stock is currently available for trading in the over-the-counter market and is quoted on the OTC Bulletin Board under the symbol NVIV . The last sale price of our common stock on June 29, 2011 was $1.00.

These are speculative securities. Investing in our securities involves significant risks. You should purchase these securities only if you can afford a complete loss of your investment. See Risk Factors beginning on page 6.

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

The date of this prospectus is , 2011.

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

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PROSPECTUS SUMMARY

The following summary highlights selected information contained in this prospectus. This summary does not contain all the information that may be important to you. You should read the more detailed information contained in this prospectus, including but not limited to, the risk factors beginning on page 6. References to we, us, our, or the Company refer to InVivo Therapeutics Holdings Corp., together, with its consolidated subsidiaries where applicable. The term ITHC refers to InVivo Therapeutics Holdings Corp. (f/k/a Design Source, Inc.), the Nevada corporation, before giving effect to the Merger, and the term InVivo refers to InVivo Therapeutics Corporation, the Delaware corporation, before giving effect to the Merger.

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

The Merger and Related Transactions

On October 4, 2010, we merged into our newly formed, wholly owned subsidiary, InVivo Therapeutics Holdings Corp. (ITHC). The sole purpose of this merger was to effect a change of our name from Design Source, Inc. to InVivo Therapeutics Holdings Corp. in anticipation of a business acquisition.

On October 26, 2010, InVivo Therapeutics Acquisition Corp., our wholly-owned subsidiary, merged (the Merger) with and into InVivo Therapeutics Corporation, a Delaware corporation (InVivo). InVivo was the surviving corporation of that Merger. As a result of the Merger, we acquired the business of InVivo, and will continue the existing business operations of InVivo, as a wholly-owned subsidiary.

Simultaneously with the Merger, all of the issued and outstanding shares of InVivo common stock converted, on a 13.7706 for 1 basis, into shares of our common stock par value $0.00001 per share (the Common Stock). All of the issued and outstanding options to purchase shares of InVivo common stock, and the issued and outstanding Bridge Warrants (as defined below) to purchase shares of InVivo common stock, converted, respectively, into options (the New Options) and new bridge warrants (the New Bridge Warrants) to purchase shares of our Common Stock. The number of shares of Common Stock issuable under, and the price per share upon exercise of, the New Options and the New Bridge Warrants were calculated based on the terms of the original options and warrants of InVivo, as adjusted by the conversion ratio in the Merger, which is described in the Merger Agreement. The New Options will be administered under InVivo s 2007 Stock Incentive Plan, which the Company assumed and adopted in connection with the Merger.

An aggregate of 31,647,190 shares of Common Stock were issued to former InVivo stockholders and options for the purchase of 5,915,557 shares of Common Stock and New Bridge Warrants for the purchase of 600,000 shares of Common Stock were issued to holders of outstanding InVivo options and warrants. Our stockholders before the Merger, without giving effect to the Offering (as defined below), retained 6,999,981 shares of Common Stock.

The Merger was a reverse merger, and InVivo is deemed to be the acquirer and ongoing operating company. The Merger was recorded as a recapitalization of InVivo, equivalent to the issuance of common stock by InVivo for the net monetary assets of ITHC accompanied by a recapitalization. At the date of the Merger, the 6,999,981 outstanding ITHC shares are reflected as an issuance of InVivo common stock to the prior shareholders of ITHC. ITHC had no net monetary assets as of the Merger so this issuance was recorded as a reclassification between additional paid-in capital and par value of Common Stock. In connection with the Merger, we adopted the fiscal year end of InVivo, thereby changing our fiscal year end from March 31 to December 31.

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In connection with the Merger, on October 26, November 10 and December 3, 2010, we completed a private offering (the Offering) of 13,000,000 units of our securities (Units), at a price of $1.00 per Unit. Each Unit consists of one share of Common Stock and a warrant to purchase one share of Common Stock. The warrants (the Investor Warrants) are exercisable for a period of five years at a purchase price of $1.40 per share of Common Stock. The Offering was made only to accredited investors, as defined under Regulation D, Rule 501(a). The investors in the Offering collectively purchased 13,000,000 Units for total cash consideration of $13,000,000, which includes the conversion of $504,597 of principal of, and accrued interest on, Bridge Notes (as defined below) and we received net proceeds after expenses of $10,914,044.

We paid Spencer Trask Ventures, Inc., our placement agent in the Offering (the Placement Agent), a commission of 10% of the funds raised from investors in the Offering. In addition, the Placement Agent received a non-accountable expense allowance equal to 3% of the proceeds raised in the Offering as well as warrants to purchase a number of shares of Common Stock equal to 20% of the Common Stock and 20% of the Common Stock underlying the Investor Warrants sold to investors in the Offering. As a result of the foregoing arrangement, the Placement Agent was paid commissions and expenses of $1,690,000 and was issued warrants to purchase (i) 2,600,000 shares of Common Stock at an exercise price of $1.00 per share and (ii) 2,600,000 shares of Common Stock at an exercise price of $1.40 per share. Neither the warrants nor the shares issuable upon exercise of the warrants issued to the Placement Agent have registration rights and such securities are not being registered on this registration statement. The warrants contain weighted average anti-dilution and immediate cashless exercise provisions. In September 2010, several related parties to the Placement Agent purchased an aggregate of 3,895,643 shares of our Common Stock from various shareholders of the Company at an aggregate cost of $49,000.

Prior to the Merger, InVivo completed a Bridge Financing, wherein it sold $500,000 in principal amount of its bridge notes (the Bridge Notes) and 36,310 bridge warrants (the Bridge Warrants) to accredited investors (the Bridge Financing). The Bridge Notes converted into 504,597 Units in the Offering. The 36,310 Bridge Warrants converted into 500,000 New Bridge Warrants, each exercisable at a price of $1.00 per share of Common Stock, upon the closing of the Merger. As consideration for identifying investors to participate in the Bridge Financing, the Placement Agent received Warrants from InVivo that were exchanged on the closing of the Merger for Warrants to purchase 100,000 shares of our Common Stock at a price of $1.00 per share. The Placement Agent also received, upon conversion of the Bridge Notes, compensation in the same amount as it received for other Units sold in the Offering. The Merger, the Offering, the Bridge Financing and the related transactions are collectively referred to in this prospectus as the Transactions.

Simultaneously with the closing of the Merger on October 26, 2010, ITHC transferred all of its operating assets and liabilities to its wholly-owned subsidiary, D Source Split Corp., a company organized under the laws of Nevada (DSSC). DSSC was then split-off from ITHC through the sale of all outstanding shares of DSSC (the Split-Off). In connection with the Split-Off, 14,747,554 shares of our Common Stock held by Peter Reichard, Lawrence Reichard and Peter Coker (the Split-Off Shareholders) were surrendered and cancelled without further consideration, other than the shares of DSSC. An additional 1,014,490 shares of our Common Stock were cancelled by a shareholder for no additional consideration. The assets and liabilities of ITHC were transferred to the Split-Off Shareholders in the Split-Off. ITHC executed a split off agreement with the Split-Off Shareholders which obligates the Split-Off Shareholders to assume all prior liabilities associated with ITHC before the Merger.

Please see Description of Capital Stock on page 60 for a reconciliation of the outstanding shares of InVivo and ITHC common stock on a pre and post Merger basis.

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Business Overview

InVivo was founded in 2005 to develop and commercialize new technologies for the treatment of spinal cord injuries. InVivo s proprietary technology was co-invented by Robert S. Langer, ScD, Professor at Massachusetts Institute of Technology and Joseph P. Vacanti, MD, affiliated with Massachusetts General Hospital. The intellectual property rights that are the basis for our products are licensed under an exclusive, world-wide license from Children s Medical Center Corporation (CMCC) and Massachusetts Institute of Technology (MIT).

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

Currently, there are no successful spinal cord injury treatment options for spinal cord injury patients. We take a different approach to spinal cord injury and focus on protection of the spinal cord and prevention of secondary injury rather than regeneration. Our platform technologies focus on minimizing tissue damage sustained following acute injury and promoting neural plasticity of the spared healthy tissue, which may result in full or partial functional recovery. The technologies encompass multiple strategies involving biomaterials, U.S. Food & Drug Administration (FDA) approved drugs, growth factors, and human neural stem cells. We believe our approach could become a standard treatment for both acute and chronic spinal cord injuries.

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

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

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

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

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

The Company s first product, the biocompatible polymer scaffolding device to treat acute spinal cord injuries is expected to be regulated by the FDA as a Class III medical device. A Class III medical device will require FDA approval of a Pre-Market Approval Application (PMA) before the Company can start selling the product in the U.S.

The Company will be required to demonstrate safety and efficacy in human clinical studies before it can submit a PMA to the FDA. Before clinical studies can commence, the Company must submit an Investigational Device Exemption application (IDE) to the FDA and the FDA must approve the IDE. The Company intends to submit an IDE application for its biopolymer scaffolding device before the end of July 2011. 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 Company is provided the opportunity to provide additional information to the FDA to respond to the filing deficiencies. The Company anticipates that its IDE will be approved by the FDA by the end of 2011. The Company plans to first conduct a pilot study in ten acute spinal cord patients followed by a larger pivotal study.

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The completion of the human clinical studies and the FDA approval of the PMA could take between three to five years to achieve, depending on a number of factors including the FDA review and clearance process for the IDE, the clinical trial designs and amount of time it will take to enroll and treat patients, and the FDA review and approval process for the PMA. The FDA regulatory approval process is lengthy, and the outcome is highly uncertain. The risk exists that the first product may never be approved, or that the approval is significantly delayed such that the Company is unable to raise additional capital to continue to fund the Company. Please see Risk Factors beginning on page 6 for a more detailed discussion of these risks.

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

Additional applications of our platform technologies include the potential treatment for, spinal cord injury following tumor removal, peripheral nerve damage, and postsurgical treatment of any transected nerve. Our first product, the biocompatible scaffolding device for the treatment of acute spinal cord injury, is regulated as a Class III medical device by the FDA. The product has been evaluated in animal studies and the Company intends to submit an Investigational Device Exemption with the FDA during 2011 that if approved by the FDA will permit the commencement of human clinical studies.

The biocompatible hydrogel for the local release of methylprednisolone to treat acute spinal cord injuries and the biocompatible polymer scaffolding device seeded with autologous human neural stem cells to treat acute and chronic spinal cord injuries are likely to be regulated as combination drug/devices and as such will require significantly longer regulatory approval times than the biopolymer scaffolding device.

At December 31, 2010, the Company had total assets of $9,379,000 and total liabilities of $11,232,000, resulting in a stockholders deficit of $1,853,000. At March 31, 2011, the Company had total assets of approximately $7,984,000 and total liabilities of approximately $11,005,000, resulting in a stockholders deficit of $3,021,000. At March 31, 2011, the Company had incurred net losses of approximately $14,367,000 since inception.

Offering by Selling Securityholders

We are registering the following securities issued in connection with the Offering and Bridge Financing:

For resale by the selling securityholders, 12,848,600 shares of Common Stock purchased in the Offering;

For resale by the selling securityholders, 12,848,600 shares of Common Stock issuable upon exercise of the Investor Warrants that were acquired in the Offering; and

For resale by the selling securityholders, 350,000 shares of Common Stock issuable upon exercise of the New Bridge Warrants.

As of the date of this prospectus, each Investor Warrant and New Bridge Warrant is exercisable to purchase one share of Common Stock. The exercise price and number of shares of Common Stock issuable upon exercise of the Investor Warrants and the New Bridge Warrants are subject to further adjustment in certain circumstances.

The exercise price of each Investor Warrant is $1.40. The Investor Warrants expire on varying dates up to December 3, 2015. There is a possibility that the warrants will never be exercised when in-the-money or otherwise, and that warrant holders will never receive shares or payment of cash in settlement of the warrants.

The Investor Warrants may be redeemed by us at any time our Common Stock trades above $2.80 for twenty consecutive days following the effectiveness of the registration statement covering the resale of the underlying Investor Warrant shares. The Investor Warrants can only be redeemed if this registration statement is effective at the time of the redemption notice.

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The exercise price of each New Bridge Warrant is $1.00. The New Bridge Warrants expire on October 26, 2015. There is a possibility that the warrants will never be exercised when in-the-money or otherwise, and that warrant holders will never receive shares or payment of cash in settlement of the warrants. We do not have the right to redeem the New Bridge Warrants.

Common stock outstanding	51,674,712 shares as of June 29, 2011
Use of proceeds	We will not receive any of the proceeds from the sale of the securities being registered on behalf of the Selling Securityholders hereunder. We will receive the exercise price upon the exercise of any Investor Warrant or New Bridge Warrant.
OTC Bulletin Board symbol	NVIV
Risk factors	Investing in our Common Stock involves a high degree of risk. As an investor you should be able to bear a complete loss of your investment. You should carefully consider the information set forth in the Risk Factors section of this prospectus.

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

We will bear the expenses of registering these securities. The Selling Securityholders will pay the cost of any brokerage commissions and discounts, and all expenses incurred by them in connection with the resale of the securities. See Plan of Distribution.

We had 51,674,712 shares of Common Stock issued and outstanding as of June 29, 2011. Unless the context indicates otherwise, all share and per-share Common Stock information in this prospectus:

- assumes no additional exercises of the Investor Warrants and New Bridge Warrants;
- assumes no additional exercises of the Placement Agent s warrants;
- excludes 5,888,016 shares underlying outstanding options under our 2007 Stock Incentive Plan; and
- excludes 535,000 shares underlying outstanding options under our 2010 Equity Incentive Plan.

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RISK FACTORS

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

Risks Relating to Our Business and Our Industry

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

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

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

We have not generated any revenues to date and have a history of losses since inception.

We have not generated any revenue to date and, through March 31, 2011, have incurred net losses of approximately $14,367,000 since inception. It can be expected that we will continue to incur significant operating expenses and continue to experience losses in the foreseeable future. As a result, we cannot predict when, if ever, we might achieve profitability and cannot be certain that we will be able to sustain profitability, if achieved.

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

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

- the progress and costs of our research and development programs, including our ability to develop our current portfolio of therapeutic products, or discover and develop new ones;
- our ability, or our partners ability and willingness, to advance partnered products or programs;
- the cost of prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the progress, scope, costs, and results of our preclinical and clinical testing of any current or future products;
- the time and cost involved in obtaining regulatory approvals;

the cost of manufacturing our product candidates;

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expenses related to complying with Good Manufacturing Practice manufacturing of product candidates;

costs of financing the purchases of additional capital equipment and development technologies;

competing technological and market developments;

our ability to establish and maintain collaborative and other arrangements with third parties to assist in bringing our products to market and the cost of such arrangements.

the amount and timing of payments or equity investments that we receive from collaborators and the timing and amount of expenses we incur;

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

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

the level of our sales and marketing expenses; and

our ability to introduce and sell new products.

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

Our products will represent new and rapidly evolving technologies.

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

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

We license patents and core intellectual property from CMCC and MIT under the CMCC license. The CMCC license agreement imposes certain payment, milestone achievement, reporting, confidentiality and other obligations on us. In the event that we were to breach any of the obligations and fail to cure, CMCC would have the right to terminate the CMCC license agreement upon notice. In addition, CMCC has the right to terminate the CMCC license agreement upon the bankruptcy or receivership of the Company. The termination of the CMCC license would 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,

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academic institutions, government agencies and private and public research institutions. Many of these competitors have significantly greater financial and technical resources than us, and superior experience and expertise in research and development, preclinical testing, designing and implementing clinical trials, regulatory processes and approvals, production and manufacturing, and sales and marketing of approved products.

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

Large and established companies compete in the biotech market. In particular, these companies have greater experience and expertise in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale and marketing approved products.

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

In order to effectively compete, we will have to make substantial investments in development, testing, manufacturing and sales and marketing or partner with one or more established companies. There is no assurance that we will be successful in having our products approved or gaining significant market share for any of our products. Our technologies and products also may be rendered obsolete or noncompetitive as a result of products introduced by our competitors.

We will require FDA approval before we can sell any of our products.

The development, manufacture and marketing of our products are subject to government regulation in the United States and other countries. In the United States and most foreign countries, we must complete rigorous preclinical testing and extensive human clinical trials that demonstrate the safety and efficacy of a product in order to apply for regulatory approval to market the product.

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

The processes are expensive and can take many years to complete, and we may not be able to demonstrate the safety and efficacy of our products to the satisfaction of such regulatory authorities. The start of clinical trials can be delayed or take longer than anticipated for many and varied reasons, many of which would be outside of our control. All statutes and regulations governing the conduct of clinical trials are subject to change in the future, which could affect the cost of such clinical trials. Safety concerns may emerge that could lengthen the ongoing trials or require additional trials to be conducted. Regulatory agencies may require us or our collaborators to delay, restrict or discontinue clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Regulatory authorities may also require additional testing, and we may be required to demonstrate that our proposed products represent an improved form of treatment over

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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.

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.

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Approval to promote, manufacture and/or sell our products, if granted, will be limited and subject to continuing review.

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

We also may be restricted or prohibited from marketing or manufacturing a product, even after obtaining product approval, if previously unknown problems with the product or its manufacture are subsequently discovered and we cannot provide assurance that newly discovered or developed safety issues will not arise following any regulatory approval. With the use of any treatment by a wide patient population, serious adverse events may occur from time to time that initially do not appear to relate to the treatment itself, and only if the specific event occurs with some regularity over a period of time does the treatment become suspect as having a causal relationship to the adverse event. Any safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenues.

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

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

We will depend upon strategic relationships to develop, exploit and manufacture our products.

The near and long-term viability of our products will depend in part on our ability to successfully establish new strategic collaborations with biotechnology companies, hospitals, insurance companies and government agencies. Establishing strategic collaborations is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position. If we fail to establish a sufficient number of collaborations on acceptable terms, we may not be able to commercialize our products or generate sufficient revenue to fund further research and development efforts.

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

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

Completion of our clinical trials and commercialization of our products will require access to, or development of, facilities to manufacture a sufficient supply of our product or other product candidates. If we are unable to 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

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able to enter into any necessary third-party manufacturing arrangements on acceptable terms, or on a timely basis. Failure by us to manufacture products on a timely basis for clinical trials or for commercial needs will have a material adverse affect on us.

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

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

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

We have been and will continue to be dependent on third-party contract research organizations to conduct some of our laboratory testing, animal and human studies. If we are unable to obtain any necessary testing services on acceptable terms, we may not complete our product development efforts in a timely manner. If we rely on third parties for laboratory testing and/or animal and human studies, we may lose some control over these activities and become too dependent upon these parties. These third parties may not complete testing activities on schedule or when we request. We may not be able to secure and maintain suitable contract research organizations to conduct our laboratory testing and/or animal and human studies. We are responsible for confirming that each of our clinical trials is conducted in accordance with our general plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our product candidates.

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

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

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

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

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assurance that existing insurance coverage will extend to other products in the future. Any product liability insurance coverage may not be sufficient to satisfy all liabilities resulting from product liability claims. A successful claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable items, if at all. Even if a claim is not successful, defending such a claim would be time-consuming and expensive, may damage our reputation in the marketplace, and would likely divert management s attention.

Our products are new and will require market acceptance.

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

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

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

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

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

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

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

Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

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

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

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

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

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

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

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

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We are dependent on our management and other key personnel.

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

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

Risks Related to Investment in Our Securities

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

The SEC has adopted Rule 15g-9 which establishes the definition of a penny stock, for the purposes relevant to us, as any equity security that has