INVIVO THERAPEUTICS HOLDINGS CORP.
Form 424B5
February 17, 2012
Table of Contents

Filed Pursuant to Rule 424(b)(5)

Registration No. 333-178584

PROSPECTUS SUPPLEMENT

(To Prospectus dated January 19, 2012)

8,281,574 Shares of Common Stock

INVIVO THERAPEUTICS HOLDINGS CORP.

We are offering 8,281,574 shares of our common stock pursuant to this prospectus supplement and the accompanying prospectus.

Our common stock is quoted on the OTC Bulletin Board under the symbol NVIV.OB. The last reported sale price of our common stock on February 16, 2012 was $2.42 per share.

Our business and an investment in our common stock include significant risks. See Risk Factors on page S-6 of this prospectus supplement and on page 5 of the accompanying prospectus, as well as in our periodic reports filed with the Securities and Exchange Commission and incorporated by reference in this prospectus supplement and the accompanying prospectus.

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

	Per Share	Total
Public offering price	$ 2.100	$ 17,391,305
Underwriting discount	$ 0.147	$ 1,217,391
Proceeds, before expenses, to us	$ 1.953	$ 16,173,914

The underwriters may also purchase up to an additional 1,242,236 shares from us at the public offering price, less the underwriting discount, within 30 days from the date of this prospectus supplement to cover overallotments, if any. If the underwriters exercise the option in full, the total discount will be $1,400,000 and the total net proceeds, before expenses, to us will be $18,600,000.

The underwriters expect to deliver the shares against payment on or about February 23, 2012.

Aegis Capital Corp **Summer Street Research Partners**

The date of this prospectus supplement is February 16, 2012.

Table of Contents

Table of Contents

Table of Contents

Table of Contents

About This Prospectus Supplement

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering of common stock and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part, the accompanying prospectus dated January 19, 2012, including the documents incorporated by reference therein, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or in any document incorporated by reference that was filed with the Securities and Exchange Commission, or SEC, before the date of this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date for example, a document incorporated by reference in the accompanying prospectus the statement in the document having the later date modifies or supersedes the earlier statement.

You should rely only on the information contained in or incorporated by reference in this prospectus supplement and the accompanying prospectus. We have not, and the underwriters have not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus supplement, the accompanying prospectus, and the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, the accompanying prospectus, and the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, in their entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the sections of this prospectus supplement entitled Where You Can Find More Information and Incorporation of Certain Information by Reference.

Unless otherwise mentioned or unless the context requires otherwise, all references in this prospectus supplement to InVivo Therapeutics, InVivo, the Company, our company, we, us, our or similar references mean collectively InVivo Therapeutics Holdings Corp. and its subsidiaries.

This prospectus supplement, the accompanying prospectus and the information incorporated herein and therein by reference include trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included or incorporated by reference into this prospectus supplement or the accompanying prospectus are the property of their respective owners.

Table of Contents

Prospectus Supplement Summary

This summary highlights certain information about us, this offering and selected information contained elsewhere in or incorporated by reference into this prospectus supplement or the accompanying prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our common stock. For a more complete understanding of our company and this offering, we encourage you to read and consider carefully the more detailed information in this prospectus supplement and the accompanying prospectus, including the information incorporated by reference in this prospectus supplement and the accompanying prospectus, including the information under the heading Risk Factors in this prospectus supplement on page S-6 and in the accompanying prospectus on page 5.

InVivo Therapeutics Holdings Corp.

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.

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

Table of Contents

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 us 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, but we can give no assurance that the IDE will be approved. We plan to first conduct a pilot study in ten acute spinal cord patients followed by a larger pivotal study. The 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 5 of the accompanying prospectus 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 plan 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.

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.

Table of Contents

Recent Developments

Preliminary Results for the Year Ended December 31, 2011

Although our financial statements as of and for the year ended December 31, 2011 are not yet available, the following information reflects our estimates of our results based on currently available information.

For the year ended December 31, 2011, we expect to report the following results:

(In millions, except for per share amounts)	Estimated 12/31/2011	Actual 12/31/2010
Balance Sheet Data		
Cash	$ 4.3	$ 9.0
Warrant liability	35.2-35.7	10.6
Stockholders deficit	$ (30.9)-(31.4)	$ (1.9)
Statement of Operations Data		
Research and development	$ 3.8-4.3	$ 1.7
General and administrative	4.3-4.8	1.7
Total operating expenses	8.4-8.9	3.4
Derivative loss	(25.8)-(26.3)	(4.0)
Net loss	$ (34.4)-(34.9)	$ (7.9)
Net loss per share, basic and diluted	$ (0.66)-(0.67)	$ (0.24)
Weighted average number of common shares outstanding, basic and diluted	51.6	33.4

Research and development expenses in 2011 are expected to increase by $2.1-2.6 million over 2010, with the increase being primarily attributable to the hiring of additional personnel and an increase in costs of pre-clinical studies. General and administrative expenses in 2011 are expected to increase by $2.6-3.1 million over 2010, with the increase being primarily attributable to an increase in costs associated with operating as a public company and increases in rent, salary and benefits costs. Derivative loss in 2011 is expected to increase by $21.8-22.3 million over 2010 as a result of non-cash expense attributable to an increase in the fair value measurement of the derivative warrant liability.

The foregoing constitute forward-looking statements and should be read in light of the section of this prospectus supplement entitled Special Note Regarding Forward-Looking Information. These preliminary results are unaudited and represent our estimates only, and our actual results could differ materially and adversely from those set forth above as a result of various factors, some of which are listed in the section of the accompanying prospectus entitled Risk Factors. In addition, these factors include, without limitation, the risk that additional information may arise during our close process or as a result of subsequent events that would require us to make adjustments to the financial information, as well as the risk that adjustments to our financial statements may be identified through the course of our independent registered public accounting firm completing its audit of our financial statements.

Corporate Information

InVivo Therapeutics Corporation (InVivo Corporation) was incorporated on November 28, 2005 under the laws of the State of Delaware. On October 26, 2010, InVivo Corporation completed a reverse merger transaction with InVivo Therapeutics Holdings Corp. (formerly Design Source, Inc.), a publicly traded company incorporated under the laws of the State of Nevada. As a result of the merger, InVivo Corporation became a wholly owned subsidiary of InVivo Therapeutics Holdings Corp., which continues to operate the business of InVivo Corporation.

Table of Contents

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. Information contained on, or accessible through, our website is not a part of, and is not incorporated by reference into, this prospectus supplement or the accompanying prospectus.

Table of Contents

The Offering

Common stock offered by us	8,281,574 shares
Offering price	$2.10
Common stock outstanding immediately after this offering	62,042,035 shares
Over-allotment option	1,242,236 shares
Use of proceeds	We intend to use the net proceeds from the common stock offered hereby for general corporate purposes. See Use of Proceeds on page S-8.
Risk factors	Investing in our common stock involves significant risks. See Risk Factors on page S-6 of this prospectus supplement and on page 5 of the accompanying prospectus.
OTC Bulletin Board symbol	NVIV.OB

The number of shares of our common stock to be outstanding immediately after this offering as shown above is based on 53,760,471 shares outstanding as of December 31, 2011, and excludes as of that date:

- 18,405,975 shares of our common stock issuable upon exercise of warrants, having a weighted average exercise price of $1.42 per share;
- 6,302,893 shares of our common stock issuable upon exercise of outstanding stock options, having a weighted average exercise price of $0.76 per share;
- 2,536,259 shares of our common stock reserved for future issuances under our incentive compensation plans and 401(k) plan; and
- up to 3,100,000 shares potentially issuable to satisfy post-closing claims made before October 26, 2012 under the terms of the Agreement and Plan of Merger dated October 26, 2010.

Except as otherwise indicated, all information in the prospectus supplement assumes no exercise by the underwriters of their overallotment option.

Table of Contents

Risk Factors

An investment in our common stock involves a high degree of risk. Before deciding whether to invest in our common stock, you should consider carefully the risks described below and discussed under the section captioned Risk Factors beginning on page 5 of the accompanying prospectus, together with other information in this prospectus supplement, the accompanying prospectus, and the information and documents incorporated by reference in this prospectus supplement and the accompanying prospectus. If any of these risks actually occurs, our business, financial condition or results of operations could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

Risks Related to the Offering

Management will have broad discretion as to the use of the proceeds from this offering, and we may not use the proceeds effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the price of our common stock to decline.

If you purchase the common stock sold in this offering, you will experience immediate and substantial dilution in your investment. You will experience further dilution if we issue additional equity securities in future fundraising transactions.

Since the price per share of our common stock being offered is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution with respect to the net tangible book value of the common stock you purchase in this offering. Based on the public offering price of $2.10 per share and our net tangible book value as of September 30, 2011, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of $1.85 per share with respect to the net tangible book value of the common stock. See the section entitled Dilution on page S-9 of this prospectus supplement for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

If we issue additional common stock, or securities convertible into or exchangeable or exercisable for common stock following the expiration of the lock-up agreement we entered into with the underwriters as described in the section entitled Underwriting, our stockholders, including investors who purchase shares of common stock in this offering, could experience additional dilution, and any such issuances may result in downward pressure on the price of our common stock.

Table of Contents

Special Note Regarding Forward-Looking Information

This prospectus supplement, the accompanying prospectus and the documents we have filed with the SEC that are incorporated by reference into this prospectus supplement and the accompanying prospectus contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements may include, but are not limited to, statements about:

- the progress, timing and results of pre-clinical and clinical trials and research and development efforts involving our product candidates;
- the submission of applications for and receipt of regulatory clearances and approvals;
- our ability to commercialize our product candidates;
- our business strategy and our expectations with respect to the implementation of our business strategy;
- our expectations with respect to the potential therapeutic and commercial value of our product candidates;
- the benefits we expect to derive from relationships with our collaborators;
- our expectations with respect to our intellectual property position;
- the use of proceeds from this offering; and
- our estimates regarding our capital requirements and our need for additional financing.

In some cases, you can identify forward-looking statements by terms such as may, will, should, could, would, expects, plans, anticipa believes, estimates, projects, predicts, potential and similar expressions intended to identify forward-looking statements. These statements re our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail under the heading Risk Factors on page S-6 of this prospectus supplement and on page 5 of the accompanying prospectus and in our SEC filings. Also, these forward-looking statements represent our estimates and assumptions only as of the date of the document containing the applicable statement.

You should read this prospectus supplement, the accompanying prospectus and the documents we have filed with the SEC that are incorporated by reference into this prospectus supplement and the accompanying prospectus completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in the foregoing documents by these cautionary statements.

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

supplement, the accompanying prospectus, and the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

Table of Contents

Use of Proceeds

We estimate that the net proceeds from the sale of the 8,281,574 shares of common stock that we are offering will be approximately $15.7 million, or approximately $18.1 million if the underwriters exercise in full their option to 1,242,236 purchase up to additional shares of common stock, after deducting the underwriting discount and estimated offering expenses payable by us.

We currently intend to use the estimated net proceeds from this offering for general corporate purposes, which may include the following:

- the research, development and pre-clinical and clinical trials for our product candidates;
- the acquisition of other companies, businesses, products or technologies;
- the repayment and refinancing of debt;
- capital expenditures; and
- working capital.

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.

Table of Contents

Dilution

Our net tangible book value as of September 30, 2011 was approximately $(0.7) million, or $(0.01) per share. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of September 30, 2011. Dilution with respect to net tangible book value per share represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the net tangible book value per share of our common stock immediately after this offering.

After giving effect to the sale of 8,281,574 shares of our common stock in this offering at the public offering price of $2.10 per share and after deducting the underwriting discount and estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2011 would have been approximately $15.1 million, or $0.25 per share. This represents an immediate increase in net tangible book value of $0.26 per share to existing stockholders and immediate dilution of $1.85 per share to investors purchasing our common stock in this offering at the public offering price. The following table illustrates this dilution on a per share basis:

Public offering price per share		$ 2.10
Net tangible book value per share as of September 30, 2011	$ (0.01)	
Increase in net tangible book value per share attributable to investors purchasing our common stock in this offering	$ 0.26	
As adjusted net tangible book value per share as of September 30, 2011 after giving effect to this offering		$ 0.25
Dilution per share to investors purchasing our common stock in this offering		$ 1.85

If the underwriters exercise in full their option to purchase up to 1,242,236 additional shares of common stock, the as adjusted net tangible book value after this offering would be $0.28 per share, representing an increase in net tangible book value of $0.29 per share to existing stockholders and immediate dilution of $1.82 per share to investors purchasing our common stock in this offering at the public offering price.

The above discussion and table are based on 52,005,902 shares outstanding as of September 30, 2011, and excludes as of that date:

- 18,816,071 shares of our common stock issuable upon exercise of warrants, having a weighted average exercise price of $1.33 per share;
- 5,239,006 shares of our common stock issuable upon exercise of outstanding stock options, having a weighted average exercise price of $0.57 per share;
- 1,000,000 shares of our common stock reserved for future issuances under our incentive compensation plans;
- 980,382 shares of our common stock and a warrant to purchase 343,137 shares of our common stock sold to Ingenieria e Inversiones Ltda subsequent to September 30, 2011 on December 21, 2011; and
- up to 3,100,000 shares potentially issuable to satisfy post-closing claims made before October 26, 2012 under the terms of the Agreement and Plan of Merger dated October 26, 2010.

To the extent that outstanding options or warrants outstanding as of September 30, 2011 have been or may be exercised or other shares are issued, investors purchasing our common stock in this offering may experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

Table of Contents

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 CMCC and MIT.

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

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

The Technology

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

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

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

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

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

We will be required to demonstrate safety and efficacy in human clinical studies before we can submit a PMA to the FDA. We plan to first conduct a pilot study in ten acute spinal cord patients followed by a larger pivotal study. The FDA must review and approve the PMA before we can start selling the product in the U.S. The completion of the human clinical studies and the FDA approval of the PMA could take between three to five years to achieve, depending on a number of factors including the FDA review and clearance process for the IDE, the clinical trial designs and amount of time it will take to enroll and treat patients, and the FDA review and approval process for the PMA. The FDA regulatory approval process is lengthy, and the outcome is highly uncertain. The risk exists that the first product may never be approved, or that the approval is significantly delayed such that the we are unable to raise additional capital to continue to fund the Company. Please see Risk Factors beginning on page 5 of the accompanying prospectus for additional discussion of these risks.

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

Table of Contents

Additional applications of our platform technologies include the potential treatment for spinal cord injury following tumor removal, peripheral nerve damage, and postsurgical treatment of any transected nerve. Our first product, the biocompatible scaffolding device for the treatment of acute spinal cord injury, is regulated as a Class III medical device by the FDA. The product has been evaluated in animal studies and the Company submitted an IDE with the FDA on July 7, 2011, that if approved by the FDA will permit the commencement of human clinical studies. The FDA has provided us with comments to its IDE filing and we are in the process of responding to the FDA comments. We anticipate that our IDE will be approved by the FDA during 2012, but can give no assurance that the IDE will be approved. The biocompatible hydrogel for the local release of methylprednisolone to treat acute spinal cord injuries and the biocompatible polymer scaffolding device seeded with autologous human neural stem cells to treat acute and chronic spinal cord injuries are likely to be regulated as combination drug/devices and as such will require significantly longer regulatory approval times than the biopolymer scaffolding device.

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

Market Opportunity

As we are aware of no current products on the market that treat paralysis caused by spinal cord injuries, we believe that our market opportunity for our technology is significant. Based on the Company s estimates, the total addressable market for acute spinal cord injury is approximately $10.4 billion annually. Since 1973, the National Spinal Cord Injury Statistical Center (NSCISC) at the University of Alabama has been commissioned by the US government to maintain a national database of spinal cord injury statistics.

In the United States:

- Approximately 1,275,000 people are currently living with paralysis due to spinal cord injury.
- An additional 12,000 individuals will become fully or partially paralyzed this year alone.

The financial impact of spinal cord injuries, as reported by the NSCISC, is enormous:

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

Sources: *Christopher & Dana Reeve Foundation, and National Spinal Cord Injury Statistical Center. One Degree of Separation: Paralysis and Spinal Cord Injury in the United States 2011.*

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

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

	AVERAGE YEARLY EXPENSES (in 2010 dollars)	**ESTIMATED LIFETIME COSTS BY AGE AT INJURY** (NPV, Discounted at 2%)

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

Table of Contents

Source: *National Spinal Cord Injury Statistical Center; February 2011 edition of Spinal Cord Injury Facts and Figures at a Glance. All figures in US Dollars.*

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

Creating New Treatments for Spinal Cord Injuries

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

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

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

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

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

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

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

FIGURE 2. SCAFFOLD IMPLANTED INTO SPINAL CORD INJURY LESION

Table of Contents

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

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