

INVIVO THERAPEUTICS HOLDINGS CORP.
Form 10-K
March 17, 2014

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

[Item 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA](#)

[Table of Contents](#)

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
WASHINGTON, D.C. 20549

FORM 10-K

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2013

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934**

**FOR THE TRANSITION PERIOD FROM TO
COMMISSION FILE NUMBER 000-52089**

INVIVO THERAPEUTICS HOLDINGS CORP.

(Exact Name of Registrant as specified in its charter)

Nevada
(State or other jurisdiction of
incorporation or organization)

36-4528166
(I.R.S. Employer
Identification No.)

One Kendall Square
Suite B14402 Cambridge, Massachusetts
(Address of principal executive offices)

02139
(Zip Code)

(617) 863-5500

Registrant's telephone number, including area code:

Securities registered pursuant to Section 12(b) of the Act: **None**

Securities registered pursuant to Section 12(g) of the Act:

Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form 10-K

Title of each class	
Common Stock, par value \$	0.00001 per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates based on the closing price of such stock on the Over-the-Counter Bulletin Board (\$4.13) on June 28, 2013 was \$238,670,234.

As of March 5, 2014, the number of shares outstanding of the registrant's common stock, \$0.00001 par value per share, was 78,994,064.

DOCUMENTS INCORPORATED BY REFERENCE

Designated portions of the Registrant's Proxy Statement for its 2014 Annual Meeting of Stockholders to be filed within 120 days after the Registrant's fiscal year end of December 31, 2013 are incorporated by reference into Part III of this Annual Report.

Table of Contents

**INVIVO THERAPEUTICS HOLDINGS CORP.
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2013
TABLE OF CONTENTS**

ITEM	Page
<u>PART I</u>	
<u>1. Business</u>	<u>4</u>
<u>1A. Risk Factors</u>	<u>9</u>
<u>1B. Unresolved Staff Comments</u>	<u>20</u>
<u>2. Properties</u>	<u>20</u>
<u>3. Legal Proceedings</u>	<u>20</u>
<u>4. Mine Safety Disclosures</u>	<u>21</u>
<u>PART II</u>	
<u>5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	<u>22</u>
<u>6. Selected Financial Data</u>	<u>25</u>
<u>7. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>28</u>
<u>7A. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>34</u>
<u>8. Consolidated Financial Statements and Supplementary Data</u>	<u>35</u>
<u>9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	<u>59</u>
<u>9A. Controls and Procedures</u>	<u>59</u>
<u>9B. Other Information</u>	<u>62</u>
<u>PART III</u>	
<u>10. Directors, Executive Officers and Corporate Governance</u>	<u>62</u>
<u>11. Executive Compensation</u>	<u>62</u>
<u>12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>62</u>
<u>13. Certain Relationships and Related Transactions, and Director Independence</u>	<u>62</u>
<u>14. Principal Accountant Fees and Services</u>	<u>62</u>
<u>PART IV</u>	
<u>15. Exhibits and Financial Statement Schedules</u>	<u>63</u>

Table of Contents

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, regarding future events, our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "might," "will," "should," "intends," "expects," "plans," "goals," "projects," "anticipates," "believes," "estimates," "predicts," "potential," or "continue" or the negative of these terms or other comparable terminology, and include statements about the market potential for treatment of acute spinal cord injury, the sufficiency of our existing capital resources for continuing operations in 2014, the expected effectiveness of our products, and our ability to develop collaborations and partnerships to support our business. These forward-looking statements are only predictions, are uncertain and involve substantial known and unknown risks, uncertainties and other factors which may cause our actual results, levels of activity or performance to be materially different from any future results, levels of activity or performance expressed or implied by these forward-looking statements. Such factors include, among others, the following:

our limited operating history and history of net losses;

our ability to raise substantial additional capital to finance our planned operations;

our ability to successfully commercialize our current and future product candidates, including our bioresorbable polymer scaffold and our bioresorbable hydrogel;

our ability to successfully complete clinical trials and obtain and maintain regulatory approval of our product candidates;

our ability to protect and maintain our intellectual property;

market acceptance of our technology and products;

our ability to promote, manufacture and sell our products, either directly or through collaborative and other arrangements with third parties;

our ability to attract and retain key personnel; and

other factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K and in subsequent filings we make with the Securities and Exchange Commission.

We cannot guarantee future results, levels of activity or performance. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report on Form 10-K. These cautionary statements should be considered with any written or oral forward-looking statements that we may issue in the future. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to reflect actual results, later events or circumstances or to reflect the occurrence of unanticipated events.

As used herein, "we," "us," "our" or the "Company" means InVivo Therapeutics Holdings Corp., together with its consolidated subsidiaries, unless otherwise noted.

Table of Contents

Item 1. BUSINESS

Overview

We develop novel biomaterial technologies for the treatment of spinal cord injuries and hydrogels for therapeutics delivery. Our proprietary technologies incorporate intellectual property licensed under an exclusive, world-wide license from Children's Medical Center Corporation ("CMCC") and the Massachusetts Institute of Technology ("MIT"), and intellectual property that has been developed internally, including in collaboration with our advisors and partners. At December 31, 2013, we were considered a "development stage enterprise" and will continue to be so until we commence commercial operations. A development stage enterprise is one in which planned principal operations have not commenced or, if its operations have commenced, there has been no significant revenue from operations. Development stage companies report cumulative costs from the date of inception of the enterprise. Our development stage started on November 28, 2005 and continued through December 31, 2013. As of December 31, 2013, we have experienced total net losses since inception of approximately \$81,909,055.

We were incorporated on April 2, 2003, under the name of Design Source, Inc. On October 26, 2010, we acquired the business of InVivo Therapeutics Corporation, which was founded in 2005, and are continuing the existing business operations of InVivo Therapeutics Corporation as our wholly-owned subsidiary.

Our executive offices are located in leased premises at One Kendall Square, Suite B14402 and our phone number is 617-863-5500.

Market Opportunity

Our lead program that we are developing is intended to address the lack of successful treatments for spinal cord injuries. Current treatments for spinal cord injury 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, and we believe that the market opportunity for our technology is significant. 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 273,000 people are currently living with paralysis due to spinal cord injury and 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. According to the NSCISC's February 2013 report "Spinal Cord Injury Facts and Figures at a Glance," (i) during the first year, average "cost of care" ranges from \$340,787 to \$1,044,197, depending on the severity of the injury, (ii) the net present value ("NPV") to maintain a quadriplegic injured at age 25 for life is \$4,633,137, and (iii) the NPV to maintain a paraplegic injured at age 25 for life is \$2,265,584. 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 because current medical interventions address only the symptoms of spinal cord injury rather than the underlying neurological cause. We believe our approach could represent an important advance in the treatment for spinal cord injuries.

Product Development

Bioresorbable Polymer Scaffold Device

The first product that we are developing is a poly-l-glutamic acid/poly-l-lysine (PLGA-PLL) scaffold that will be inserted into the spinal cord at the center of the site of injury. The scaffold is

Table of Contents

made of bioresorbable materials that will break down over the course of several months, and incorporates components that promote cell adherence. We believe our scaffold will provide structural support and an environment supportive of cell survival and/or growth.

Because of the complexity of spinal cord injuries, it is likely that multi-modal therapies will be required in order to maximize positive outcomes in spinal cord injury patients. In the future, we may attempt to further enhance the performance of our scaffold by multiple combination strategies involving additional biomaterials, U.S. Food & Drug Administration ("FDA") approved drugs, growth factors, or human neural stem cells.

As noted below, we received a Humanitarian Use Device (HUD) designation for our scaffold and an Investigational Device Exemption (IDE) to begin a pilot clinical trial of our scaffold in 2013.

Pre-clinical Studies

Spinal cord injury (SCI) can result in permanent paralysis, sensory impairment, and autonomic, bowel, bladder, and sexual dysfunction. These functional deficits result from damage to or loss of cells (neurons and glia) in the affected region of the spinal cord, either from the initial mechanical trauma or through secondary mechanisms that persists for several weeks. The ability of potential treatments for SCI to mitigate loss of function or promote recovery can be evaluated in preclinical models using different species and different methods of inducing SCI. In our pre-clinical studies, we utilized both rat and non-human primate models because both exhibit a pattern of neuropathology following SCI that is similar to human SCI. Hemisection injury models, in which sections of spinal cord are surgically removed, are useful in the evaluation of treatment strategies that involve device implantation. Unilateral hemisection models preserve function on one side of the cord, resulting in improved recovery of bladder and bowel function. We therefore evaluated the bioresorbable polymer scaffold device in both rats and non-human primates with unilateral hemisection injury. Because most human SCIs are non-penetrating contusion injuries resulting from rapid compression of spinal tissue by intrusion of bone or disc material following mechanical disruption of the vertebral column, we also evaluated the bioresorbable polymer scaffold device in a rat model of spinal contusion injury.

The first pre-clinical study was conducted by founding scientists of our wholly-owned subsidiary in rats with surgically induced unilateral spinal cord hemisection injury. This study (see Teng, Y. D., Lavik, E. B., Qu, X., Park, K. I., Ourednik, J., Zurakowski, D., Langer, R., and Snyder, E. Y., *Functional recovery following traumatic spinal cord injury mediated by a unique polymer scaffold seeded with neural stem cells*, Proceedings of the National Academy of Sciences 99, pg 3024-3029, 2002) demonstrated the baseline safety and efficacy of porous, biodegradable scaffolds fabricated from PLGA-PLL polymer.

A series of studies in African green monkeys was then performed in order to evaluate the bioresorbable polymer scaffold device in a non-human primate. Our first study in African green monkeys established that unilateral thoracic hemisection SCI (a new model in this species) produced a consistent functional deficit, and we observed a consistently positive response to scaffold implantation (see Pritchard, C. D., Slotkin, J. R., Yu, D., Dai, H., Lawrence, M. S., Bronson, R. T., Reynolds, F. M., Teng, Y. D., Woodard, E. J., and Langer, R. S. *Establishing a model spinal cord injury in the African green monkey for the preclinical evaluation of biodegradable polymer scaffolds seeded with human neural stem cells*, Journal of Neuroscience Methods 188, pg 258-269, 2010). We then conducted two larger studies evaluating the safety and efficacy of the bioresorbable polymer scaffold device in the African green monkey. The extent and time course of functional recovery in biopolymer implant treated primates was assessed with video capture and KinemaTracer evaluation of locomotor behavior with synchronous EMG recording along with locomotor observation rating. When the results of these two studies were combined and analyzed together, we found that implantation of the bioresorbable polymer scaffold device resulted in an increase in remodeled tissue in the region of the hemisection compared

Table of Contents

to non-implant controls, and improved recovery of locomotion in subjects with full unilateral hemisection lesions. A manuscript describing the results from these studies is in preparation.

In parallel with the non-human primate studies, several studies were undertaken to evaluate the safety and efficacy of implantation of the bioresorbable polymer scaffold device following spinal cord contusion injury in rats. Initial studies indicated that 24 hours after contusion injury was an appropriate time for device implantation based on both histological evaluation and ex vivo MRI techniques. Based on these results, a larger rat contusion study was performed at our laboratory. Functional recovery was evaluated with the 21-point Basso, Beattie, and Bresnahan (BBB) locomotor rating scale to assess open field locomotion. In this experiment, the BBB score was not improved by the scaffold device. Taken together, the results from these pre-clinical studies in two injury models in the rat, and in a unilateral hemisection injury in the African green monkey, suggest that implantation of the bioresorbable polymer scaffold device can be tolerated. Further study is ongoing to assess the functional therapeutic potential of the scaffold in animal models of spinal cord contusion injury.

Second-Generation Potential

Because initial pre-clinical studies indicate the potential for use of bioresorbable polymer scaffold devices as part of a strategy to treat SCI, we intend to evaluate second-generation bioresorbable polymer scaffold devices. For example, such second-generation devices might have novel chemistries and geometries that are optimized to support the survival of cell types, like human neural stem cells, that have been shown to promote recovery following implantation in animal models of SCI.

Bioresorbable Hydrogels

We are also developing an injectable, resorbable family of hydrogels for localized, controlled release of small molecules and proteins. Currently as we progress in select pre-clinical activities, we are reaching out to potential biopharmaceutical partners in order to identify collaborations or acquisitions that will maximize the value of our technology in combination with approved and developmental therapeutics. This technology platform encompasses a broad design space with highly tunable chemical and physical properties that allow for precise control of gel formation/degradation and drug release rates. We are exploring the use of this platform in several clinical indications including neurotrauma, postoperative pain, radicular pain, and oncology. Furthermore, there are several opportunities being explored in the neurotrauma space for which the hydrogel technology could be developed as a device only (e.g. dural sealants, dural grafts, adhesion barriers).

A third party holds intellectual property, including patent rights, that may be important or necessary to the development and commercialization of certain of our hydrogel products. Accordingly, it may be necessary for us to use the patented or proprietary technology of third parties to commercialize our hydrogel products, in which case we would be required to obtain a license from such third parties or acquire such intellectual property rights. Alternatively, we can design a work-around solution or challenge the validity of such intellectual property.

Clinical/Regulatory Strategy

Our scaffold is expected to be regulated by the FDA as a Class III medical device. A Class III medical device typically will require FDA approval of a Pre-Market Approval Application (PMA) before we can begin selling the product in the United States. Alternatively, a Class III device may qualify for FDA approval to be distributed under a Humanitarian Device Exemption (HDE) rather than a PMA. In order for a device to be eligible for an HDE, it must be first designated by the FDA as a Humanitarian Use Device (HUD) intended to benefit patients in the treatment or diagnosis of a disease or condition that affects fewer than 4,000 individuals in the United States per year. The HDE also requires there must be no other comparable device available to provide therapy for this condition, and although exempt from the effectiveness requirements of a PMA, does require sufficient

Table of Contents

information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use.

We are required to conduct human clinical trials before an HDE can be submitted to the FDA to obtain evidence of safety and the probable benefit to health. Before clinical studies can commence, an Investigational Device Exemption application (IDE) must be submitted to and approved by the FDA, and the FDA. The completion of the human clinical studies and obtaining the FDA approval of a PMA could take between three to five years depending on a number of factors including the FDA review and approval process for the IDE and the clinical trial designs, the amount of time it will take to enroll and treat patients in the studies, and the FDA review and approval process for the PMA.

In 2013, the FDA approved our IDE and granted HUD designation for our scaffold. Our scaffold will be studied in an early feasibility, five subject pilot study under our approved IDE. The pilot study will be conducted with staged enrollment requiring a three month wait between consecutive subjects to allow for the monitoring of initial investigational product safety and resorption, because this is a first in human study for this type of device. The pilot study will be conducted in as many as six sites across the United States. As a result of manufacturing issues with respect to the scaffold, the Company expects that its first clinical study site will be ready to enroll subjects in the second quarter of 2014.

Following study design consideration discussions with the FDA, we are also planning a second larger pivotal clinical study in acute spinal cord injury patients.

Even if our pilot and pivotal clinical studies are successful and we are able to obtain FDA approval of a HDE for our scaffold, because the scaffold is a new unproven technology, we will have to demonstrate the clinical utility of the product and gain acceptance from physicians and obtain third party reimbursement for our product. For major markets outside the United States, we would be required to seek regulatory approvals in those markets after the clinical trials are conducted in the United States.

Intellectual Property

We rely on a combination of patents, licenses, trade secrets and non-disclosure agreements to develop, protect and maintain our intellectual property. Our patent portfolio includes patents and patent applications. We seek to develop or obtain intellectual property that we believe might be useful or complementary with our products and technologies, including by way of licenses or acquisitions of other companies or intellectual property from third parties.

As of December 31, 2013, we had filed 12 United States patent applications focused in the areas of our hydrogel technology under development that are at various stages of prosecution. In addition, we hold an exclusive worldwide license to a broad suite of patents co-owned by MIT and CMCC covering the use of a wide range of biopolymers to treat spinal cord injury, and to promote the survival and proliferation of human stem cells in the spinal cord (the "CMCC License"). Pending patent applications licensed under the CMCC License cover the technology underlying our scaffold. Issued patents and pending applications cover the use of a wide range of biomaterial scaffolding as an extracellular matrix substitute for treating spinal cord injury by itself or in combination with drugs, growth factors or human stem cells. The CMCC License covers 7 issued United States patents and 23 issued international patents expiring between 2014 and 2026, and two pending United States patents and 13 pending international patents.

The CMCC License has a 15-year term, or as long as the life of the last expiring patent right, whichever is longer, unless terminated earlier by CMCC. In connection with the CMCC License, we submitted to CMCC and MIT a 5-year plan with certain targets and projections that involve the timing of product development and regulatory approvals. We are required to meet the objectives in the plan, or else we are required to notify CMCC and revise the plan. CMCC has the right to terminate the

Table of Contents

CMCC License for failure by us to either meet the objectives in the plan or submit an acceptable revision to the plan within a 60-day cure period after notification by CMCC that we are not in compliance with the plan. Currently we are in compliance with our plan.

Under the CMCC License, we have the right to sublicense the patents and have full control and authority over the development and commercialization of the licensed products, including clinical trials, manufacturing, marketing, and regulatory filings. We also own the rights to the data generated pursuant to the CMCC License. We have the first right of negotiation for a 30-day period to any improvements to the intellectual property covered by the CMCC License.

We are required to pay certain fees and royalties under the CMCC License. We paid a license issue fee upon execution of the CMCC License and are required to pay a license amendment fee as consideration for the expansion of the field of use. We are also required to make milestone payments upon completing various phases of product development, including upon (i) FDA filing of first investigational new drug application and IDE application; (ii) enrolling first patient in Phase II testing; (iii) enrolling first patient in Phase III testing; (iv) FDA approval of first new drug application or related application, and (v) first market approval in any country outside the United States. Each year prior to the release of a licensed product, we are also required to pay a maintenance fee. Further, we are required to make payments based on sublicenses to manufacturers and distributors. Following commercialization, we are required to make ongoing royalty payments equal to a percentage of net sales of the licensed products.

Competitors

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

Manufacturing

We have developed a proprietary manufacturing process to build our scaffold. We manufacture our scaffolds following FDA requirements of Design Controls using two fully operational manufacturing cleanrooms located at our Cambridge, Massachusetts facility. These two cleanrooms are validated to ISO 14644-1 Class ISO-7 (Class 10k) and Class ISO-8 (Class 100k) cleanroom standards, respectively. In addition, the manufacturing process contains numerous quality control steps including in-process and final inspection. To date, we have only begun manufacturing our scaffold on a small scale for use in our pilot clinical study. If we are unable to scale up our manufacturing to meet requirements for our pilot or pivotal clinical studies, we may be required to rely on contract manufacturers.

Table of Contents

Sales and Marketing

If we obtain approval to commercialize our products, we plan to sell our products through a to-be-established direct sales force for major markets in the United States and through distributors in foreign markets. The direct sales force would focus its efforts on maximizing revenue through product training, placement and support. We would also seek to establish strong relationships with orthopedic spine surgeons and neurosurgeons and would expect to provide a high level of service for the products including providing on-site assistance and service during procedures. In addition, we expect to establish medical education programs to reach practitioners in physical medicine and rehabilitation centers, and through patient advocacy groups. We may also seek corporate partners with expertise in commercialization.

Compliance with Environmental, Health and Safety Laws

In addition to FDA regulations noted above, we are also subject to evolving federal, state and local environmental, health and safety laws and regulations. In the past, compliance with environmental, health and safety laws and regulations has not had a material effect on our capital expenditures. We believe that we comply in all material respects with existing environmental, health and safety laws and regulations applicable to us.

Employees

We currently have 48 employees, consisting of 45 full-time employees and 3 part-time employees. None of our employees is represented by a labor union, and we consider our employee relations to be good. We also utilize a number of consultants to assist with research and development and regulatory activities. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel.

Availability of Reports

We make available free of charge on or through the Investor Relations link on our website, www.invivotherapeutics.com, all materials that we file electronically with the Securities and Exchange Commission ("SEC"), including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after electronically filing such materials with, or furnishing them to, the SEC. During the period covered by this Form 10-K, we made all such materials available through our website as soon as reasonably practicable after filing such materials with the SEC.

You may also read and copy any materials filed by us with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549, and you may obtain information on the operation of the Public Reference Room by calling the SEC in the United States at 1-800-SEC-0330. In addition, the SEC maintains an Internet website, www.sec.gov, that contains reports, proxy and information statements and other information that we file electronically with the SEC.

Item 1A. RISK FACTORS

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

Table of Contents

Risks Relating to Our Business

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, including unforeseen capital requirements and technical problems, delays in obtaining regulatory approvals and failure of market acceptance. 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.

Table of Contents

We have not generated any revenues to date and have a history of losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

We have not generated any revenue to date and, through December 31, 2013, have incurred net losses of \$81,909,055 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.

There is substantial doubt about our ability to continue as a going concern, which will affect our ability to obtain future financing and may require us to curtail our operations.

Our financial statements as of December 31, 2013 were prepared under the assumption that we will continue as a going concern. The independent registered public accounting firm that audited our 2013 financial statements, in their report, included an explanatory paragraph referring to our recurring losses since inception and expressing substantial doubt in our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. At December 31, 2013, we had cash and cash equivalents of \$13,980,321. Our ability to continue as a going concern depends on our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue.

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 products 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 includes 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. We currently expect that our existing current capital resources will only fund operations through October of 2014. Therefore, we will need to raise substantial capital to develop our products and fund future operations. We cannot be certain that additional financing will be available on acceptable terms, or at all. If we are not successful in raising additional capital, we may not be able to continue as a going concern. To the extent we raise additional capital through the sale of equity securities, the ownership position of our existing stockholders could be substantially diluted. If additional funds are raised through the issuance of preferred stock or debt securities, these securities are likely to have rights, preferences and privileges senior to our common stock. Fluctuating interest rates could also increase the costs of any debt financing we may obtain.

Our products are in an early stage of development and will represent new and rapidly evolving technologies. If we are unable to commercialize our products or experience significant delays in doing so, our business will be materially harmed and we may have to curtail or cease our operations.

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, including the possibility that our products may be ineffective, unsafe or associated with unacceptable side effects, too expensive to develop, manufacture or market, or other parties may hold or acquire proprietary rights that could prevent us or our potential collaborators from developing or marketing our products. 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. If we are

Table of Contents

unable to obtain the required regulatory approvals of our products and subsequently commercialize them, our business will be materially harmed, and we may have to curtail or cease our operations.

If we cannot protect, maintain and, if necessary, enforce our intellectual property rights, our ability to develop and commercialize products will be adversely impacted.

Our success in large part depends on our ability to protect and maintain the proprietary nature of our technology. 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 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. The process of obtaining patents can be time consuming with no certainty of success, as a patent may not issue or may not have sufficient scope or strength to protect the intellectual property it was intended to protect. We cannot assure you that our means of protecting our proprietary rights will suffice or that our others will not independently develop competitive technology or design around patents or other intellectual property rights issued to us. Even if a patent is issued, it does not guarantee that it is valid or enforceable. Any patents that we or our licensors have obtained or obtain in the future may be challenged, invalidated or unenforceable. If necessary, we may initiate actions to protect our intellectual property, which can be costly and time consuming.

If third parties successfully claim that we infringe their intellectual property rights, our ability to continue to develop and commercialize products could be delayed or prevented.

Third parties may claim that we or our licensors are infringing on or misappropriating their proprietary information. Other organizations are engaged in research and product development efforts that may overlap with our products. Such third parties may currently have, or may obtain in the future, legally blocking proprietary rights, including patent rights, in one or more products or methods under development or consideration by us. These rights may prevent us from commercializing products, or may require us to obtain a license from the organizations to use the technology. We may not be able to obtain any such licenses that may be required on reasonable financial terms, if at all, and cannot be sure that the patents underlying any such licenses will be valid or enforceable. 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 and development of the product that is the subject of the suit. 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.

We license the technology underlying our scaffold from Children's Medical Center Corporation ("CMCC") and Massachusetts Institute of Technology ("MIT"). If a dispute with CMCC or MIT arises or if we fail to comply with the financial and other terms of the license, we could lose our rights to this license, which would result in a material harm to our business.

We license the technology underlying our scaffold under a patent license from CMCC and MIT. This 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 this license agreement upon notice. In addition, CMCC has the right to terminate this license upon the bankruptcy or receivership of the Company. The termination of this license would have a material adverse effect on our business, as our current scaffold

Table of Contents

is based on the patents and related 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 require FDA approval before we can sell any of our products in the United States and approval of similar regulatory authorities in countries outside the United States before we can sell our products in such countries. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our products if such approval is denied or delayed.

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 FDA-approval process is 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 the FDA or the regulatory authorities of other countries. Regulatory agencies may require us to delay, restrict or discontinue clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Regulatory authorities may also require additional testing, and we may be required to demonstrate that our proposed products represent an improved form of treatment over existing therapies, which we may be unable to do without conducting further clinical studies. Delays in regulatory approval can be extremely costly in terms of losing any potential marketing advantage of being early to market. 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 products, 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.

If our clinical studies are unsuccessful or significantly delayed, our ability to commercialize our scaffold will be impaired.

Before we can obtain regulatory approval for the sale of our scaffold, we must complete a pilot and pivotal clinical study. 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 scaffold undergoes clinical testing in humans. Our preclinical testing to date has been limited in nature and we cannot predict whether more extensive clinical testing will obtain similar results. Even if the results of our clinical studies in humans are promising, our scaffold may subsequently fail to meet the safety and efficacy standards required to obtain regulatory approvals.

Our pilot clinical study may not be successfully completed or may take longer than anticipated because of any number of factors, including potential delays in the start of the trial, the availability of scaffolds to supply our clinical sites, failure to demonstrate safety and efficacy, unforeseen safety issues, or unforeseen governmental or regulatory delays. Further, regulatory authorities and Institutional Review Boards that must approve and monitor the safety of any clinical study may suspend a clinical study at any time if the patients participating in such study are deemed to be exposed to any unacceptable health risk. Additionally, even if we are able to successfully complete our pilot and pivotal clinical studies, the FDA still may not approve our products.

Table of Contents

Approval to promote, manufacture and sell our products, if granted, is subject to continuing review, which may require the expenditure of substantial resources and subject us to continuing uncertainty.

Even if a product gains regulatory approval, such approval is limited to the patient population studied in our clinical trials, and the product and the manufacture 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.

We will face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

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

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 depend upon strategic relationships to develop, exploit and manufacture our products. If these relationships are not successful, we may not be able to capitalize on the market potential of these 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

Table of Contents

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 have limited experience manufacturing our scaffold for clinical-study scale and no experience for commercial scale.

We have manufactured our scaffold on a small scale, including those that will be needed for our pilot and pivotal clinical studies. We may encounter unanticipated problems in the scale-up process that will result in delays in the manufacturing of the scaffold, and therefore delay our clinical studies. We are subject to IDE FDA regulations requiring manufacturing our scaffolds following the FDA requirements of Design Controls and subject to inspections by regulatory agencies. Our failure to comply with applicable regulations may result in delays and interruptions to our product supply while we seek to secure another supplier that meets all regulatory requirements. If we are unable to scale up our manufacturing to meet requirements for our clinical studies, we may be required to rely on contract manufacturers. Reliance on third party manufacturers entails risks to which we would not be subject if we manufactured the product ourselves, including the possible breach of the manufacturing agreements by the third parties because of factors beyond our control; and the possibility of termination or nonrenewal of the agreements by the third parties because of our breach of the manufacturing agreement or based on their own business priorities.

There are a limited number of suppliers that can provide materials to us. Any problems encountered by such suppliers may detrimentally impact 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 clinical studies which exposes us to increased risk.

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 clinical 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 animal or 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 animal or human studies. We are responsible for confirming that each of our clinical trials is conducted in accordance with our approved 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

Table of Contents

extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our product candidates.

If approved, our products will require market acceptance to be successful. Failure to gain market acceptance would impact our revenues and may materially impair our ability to continue our business.

Even if we receive regulatory approvals for the commercial sale of our products, the commercial success of these products 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 products 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.

Acquisitions of companies, businesses or technologies may substantially dilute our stockholders and increase our operating losses.

We may make acquisitions of businesses, technologies or intellectual property rights that we believe would to be necessary, useful or complementary to our current business. Any such acquisition may require assimilation of the operations, products or product candidates and personnel of the acquired business and the training and integration of its employees, and could substantially increase our operating costs, without any offsetting increase in revenue. Acquisitions may not provide the intended technological, scientific or business benefits and could disrupt our operations and divert our limited resources and management's attention from our current operations, which could harm our existing product development efforts. While we may use cash or equity to finance a future acquisition, it is likely we would issue equity securities as a portion or all of the consideration in any acquisition. The issuance of equity securities for an acquisition could be substantially dilutive to our stockholders. Any investment made in, or funds advanced to, a potential acquisition target could also significantly adversely affect our results of operation and could further reduce our limited capital resources. Any acquisition or action taken in anticipation of a potential acquisition or other change in business activities could substantially depress the price of our stock. In addition, our results of operations may suffer because of acquisition-related costs or the post-acquisition costs of funding the development of an acquired technology or product candidates or operation of the acquired business, or due to amortization or impairment costs for acquired goodwill and other intangible assets.

Physicians and hospitals will require training in order to utilize our products and our success depends upon the acceptance and adoption of our products by physicians and hospitals.

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.

If we obtain approval for our products, their commercial success will depend in part upon the level of third party reimbursement for the cost of our products to users.

The commercial success of any product will depend, in part, on the extent to which reimbursement for the costs of the products and related treatments will be available from third-party payers such as

Table of Contents

government health administration authorities, private health insurers, managed care programs, and other organizations. 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 are subject to environmental, health and safety laws. Failure to comply with such environmental, health and safety laws could cause us to become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

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. We also cannot accurately predict the extent of regulations that might result from any future legislative or administrative action. Any of these laws or regulations could cause us to incur additional expense or restrict our operations. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs.

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

Our success depends on our ability to retain our management and other key personnel.

We depend on our senior management 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 our senior 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.

Table of Contents

Risks Related to Investment in Our Securities

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

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

In order to approve a person's account for transactions in penny stocks, the broker or dealer must obtain financial information and investment experience objectives of the person; and make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks. The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form sets forth the basis on which the broker or dealer made the suitability determination; and that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

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

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

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

Applicable regulatory requirements, including those contained in and issued under the Sarbanes-Oxley Act of 2002, may make it difficult for us to retain or attract qualified officers and directors, which could adversely affect the management of our business and our ability to obtain or retain listing of our common stock.

We may be unable to attract and retain those qualified officers and directors required to provide for effective management because of the rules and regulations that govern publicly held companies. The perceived increased personal risk associated with serving as an officer or director of a publicly held company may deter qualified individuals from accepting roles as directors and executive officers.

In addition, we may have difficulty attracting and retaining directors with the requisite qualifications. If we are unable to attract and retain qualified officers and directors, the management of our business and our ability to obtain or retain listing of our shares of common stock on a national securities exchange (assuming we elect to seek and are successful in obtaining such listing) could be adversely affected.

Table of Contents

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

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

actual or anticipated variations in our operating results;

announcements of developments by us or our competitors;

the completion and/or results of our clinical trials;

regulatory actions regarding our products;

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

adoption of new accounting standards affecting our industry;

additions or departures of key personnel;

introduction of new products by us or our competitors;

sales of our common stock or other securities in the open market; and

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

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

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

As of December 31, 2013, there were outstanding warrants to purchase 3,283,134 shares of our common stock, and outstanding options to purchase 8,055,522 shares of our common stock. We expect to issue additional equity awards to compensate employees, consultants and directors, and may issue additional shares to raise capital, to acquire other companies or technologies, to pay for services, or for other corporate purposes. Any such issuances will have the effect of diluting the interest of current stockholders. The future issuance of any such additional shares of common stock may create downward pressure on the trading price of the common stock. There can be no assurance that we will not be required to issue additional shares, warrants or other convertible securities in the future in conjunction with any capital raising efforts, including at a price (or exercise prices) below the price at which shares of our common stock are currently traded on the OTC Bulletin Board.

Anti-takeover effects of certain provisions of our articles of incorporation and Nevada state law may discourage or prevent a takeover.

Our articles of incorporation divide the board of directors into three classes, with three-year staggered terms. The classified board provision could increase the likelihood that, in the event an outside party acquired a controlling block of our stock, incumbent directors nevertheless would retain their positions for a substantial period, which may have the effect of discouraging, delaying or preventing a change in control. In addition, Nevada has a business combination law, which prohibits certain business combinations between Nevada corporations and "interested

stockholders" for three years after the interested stockholder first becomes an interested stockholder, unless the corporation's board of directors approves the combination in advance. In addition, we may become subject to

Table of Contents

Nevada's control share laws. A corporation is subject to Nevada's control share law if it has more than 200 stockholders, at least 100 of whom are stockholders of record and residents of Nevada, and if the corporation does business in Nevada, including through an affiliated corporation. This control share law may have the effect of discouraging corporate takeovers. Currently, we have less than 100 stockholders of record who are residents of Nevada, and are therefore not subject to the control share laws.

The provisions of our articles of incorporation and Nevada's business combination and control share laws make it more difficult for a third party to acquire us and make a takeover more difficult to complete, even if such a transaction were in our stockholders' interest or might result in a premium over the market price for our common stock.

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

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

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

On November 30, 2011 and as amended on September 17, 2012, we executed a commercial lease for 26,150 square feet of office, laboratory and manufacturing space in Cambridge, Massachusetts for a period of six years and three months with one five year extension that commenced on June 2012.

Item 3. LEGAL PROCEEDINGS

From time to time we may be named in claims arising in the ordinary course of business. Currently, no legal proceedings, government actions, administrative actions, investigations or claims are pending against us or involve us that, in the opinion of our management, could reasonably be expected to have a material adverse effect on our business and financial condition. We anticipate that we will expend significant financial and managerial resources in the defense of our intellectual property rights in the future if we believe that our rights have been violated. We also anticipate that we will expend significant financial and managerial resources to defend against claims that our products infringe upon the intellectual property rights of third parties.

In November 2013, we filed a lawsuit against Francis Reynolds, the Company's former Chairman, Chief Executive Officer and Chief Financial Officer, in Middlesex Superior Court, Middlesex County, Massachusetts (InVivo Therapeutics Holdings Corp. v. Reynolds, Civil Action No. 13-5004). The complaint alleges breaches of fiduciary duties, breach of contract, conversion, misappropriation of corporate assets, unjust enrichment, corporate waste, and seeks money damages and an accounting. The lawsuit involves approximately \$500,000 worth of personal and/or exorbitant expenses that the Company alleges Mr. Reynolds inappropriately caused the Company to pay while he was serving as the Company's Chief Executive Officer, Chief Financial Officer, President and Chairman of the Board of Directors. On December 6, 2013, Mr. Reynolds answered the complaint, and filed counterclaims against the Company and its Board of Directors. The counterclaims allege two counts of breach of contract, two counts of breach of the covenant of good faith and fair-dealing, and tortious interference with a contract, and seek monetary damages and a declaratory judgment. The counterclaims involve Mr. Reynolds's allegations that the Company and the Board interfered with the performance of his duties under the terms of his employment agreement, and that Mr. Reynolds was entitled to additional shares upon the exercise of certain stock options. On January 9, 2014, the Company and directors named in the counterclaims filed their answer. We expect discovery to begin soon. No judgments or

Table of Contents

rulings are pending at this early stage. We do not believe that the pending actions will materially impact the financial condition of the Company.

On November 8, 2012, we filed a lawsuit (InVivo Therapeutics Corp. v. Beal and Company, Inc., and RB Kendall Fee, LLC, Civil Action No. SUCV2012-04105-A) in Suffolk Superior Court, Suffolk County, Massachusetts. On September 4, 2013, we entered into a settlement agreement and on September 18, 2013, we filed a Stipulation of Dismissal with Suffolk Superior Court which settled this litigation.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Table of Contents**PART II****Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.***Market Information*

Our Common Stock is quoted on the OTC Bulletin Board under the symbol "NVIV." Our shares of Common Stock began being quoted on the OTC Bulletin Board under the symbol "NVIV" effective October 29, 2010.

The following table contains information about the range of high and low bid prices for our Common Stock for each quarter during the last two years based upon quotations on the OTC Bulletin Board.

Fiscal Quarter Ended	High Bid	Low Bid
December 31, 2012	\$ 1.95	\$ 1.28
September 30, 2012	\$ 2.66	\$ 1.36
June 30, 2012	\$ 2.64	\$ 1.96
March 31, 2012	\$ 2.94	\$ 2.00

Fiscal Quarter Ended	High Bid	Low Bid
December 31, 2013	\$ 2.49	\$ 1.08
September 30, 2013	\$ 6.20	\$ 0.94
June 30, 2013	\$ 4.75	\$ 2.20
March 31, 2013	\$ 2.59	\$ 1.61

The source of these high and low prices was the OTC Bulletin Board. These quotations reflect inter-dealer prices, without retail mark-up, markdown or commissions and may not represent actual transactions. The high and low prices listed have been rounded up to the next highest two decimal places.

On March 5, 2014, the closing bid price of our Common Stock as reported by the OTC Bulletin Board was \$2.51 per share.

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

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

Table of Contents

have the effect of reducing the level of trading activity in the secondary market for shares of Common Stock. As a result of these rules, investors may find it difficult to sell their shares.

Dividends

We have never declared or paid cash dividends. We do not intend to pay cash dividends on our Common Stock for the foreseeable future, but currently intend to retain any future earnings to fund the development and growth of our business. The payment of cash dividends if any, on the Common Stock will rest solely within the discretion of our board of directors and will depend, among other things, upon our earnings, capital requirements, financial condition, and other relevant factors.

Record Holders

As of March 5, 2014, there are approximately 338 record holders of shares of Common Stock.

Equity Compensation Plans

Information regarding our equity compensation plans and the securities authorized under the plans is included in Item 12 below.

Recent Sales of Unregistered Securities

None

Performance Graph

The graph below compares InVivo Therapeutics Holdings Corp's cumulative 38-Month cumulative total shareholder return on common stock with the cumulative total returns of the NASDAQ Composite index and the NASDAQ Biotechnology index. The graph tracks the performance of a \$100 investment in our common stock and in each index (with the reinvestment of all dividends) from 10/29/2010 to 12/31/2013.

Table of Contents

COMPARISON OF 38 MONTH CUMULATIVE TOTAL RETURN*
 Among InVivo Therapeutics Holdings Corp, the NASDAQ Composite Index,
 and the NASDAQ Biotechnology Index

*

\$100 invested on 10/29/10 in stock or 10/31/10 in index, including reinvestment of dividends. Fiscal year ending December 31.

	10/29/10	12/10	12/11	12/12	12/13
InVivo Therapeutics Holdings Corp	100.00	83.33	101.85	64.44	85.04
NASDAQ Composite	100.00	105.64	106.11	123.88	175.53
NASDAQ Biotechnology	100.00	101.49	114.21	152.38	259.25

The stock price performance included in this graph is not necessarily indicative of future stock price performance.

Table of Contents**Item 6. SELECTED FINANCIAL DATA**

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)
Consolidated Balance Sheets

	December 31,				
	2013	2012	2011	2010	2009
ASSETS :					
Current assets:					
Cash and cash equivalents	\$ 13,980,321	\$ 12,825,090	\$ 4,363,712	\$ 8,964,194	\$ 226,667
Restricted cash	601,471	601,351	547,883		
Prepaid expenses and other current assets	20,087	143,867	104,022	81,166	10,898
Total current assets	14,601,879	13,570,308	5,015,617	9,045,360	237,565
Property and equipment, net	2,337,210	2,311,942	520,482	280,181	173,797
Other assets	157,355	179,415	166,139	53,639	58,639
Total assets	\$ 17,096,444	\$ 16,061,665	\$ 5,702,238	\$ 9,379,180	\$ 470,001
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT):					
Current liabilities:					
Accounts payable	\$ 899,260	\$ 1,152,550	\$ 567,195	\$ 336,945	\$ 81,175
Loan payable-current portion	73,987		50,578		
Capital lease payable-current portion	2,799	32,606	30,724		
Derivative warrant liability		14,584,818	35,473,230	10,647,190	
Accrued expenses	1,292,185	1,021,275	618,369	247,547	577,192
Total current liabilities	2,268,231	16,791,249	36,740,096	11,231,682	658,367
Loan payable-less current portion	1,920,000	1,578,000	83,794		590,985
Convertible notes payable					2,840,000
Note payable-less current portion	18,497				
Capital lease payable-less current portion		2,799	38,042		
Total liabilities	4,206,728	18,372,048	36,861,932	11,231,682	4,089,352
Commitments and contingencies					
Stockholders' equity (deficit):					
Common stock, \$0.00001 par value(1)	788	659	538	516	263
Additional paid-in capital	94,798,231	40,842,339	16,656,830	11,235,829	1,558,283
Deficit accumulated during the development stage	(81,909,303)	(43,153,381)	(47,817,062)	(13,088,847)	(5,177,897)

Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form 10-K

Total stockholders' equity (deficit)	12,889,716	(2,310,383)	(31,159,694)	(1,852,502)	(3,619,351)
--------------------------------------	------------	-------------	--------------	-------------	-------------

Total liabilities and stockholders' equity (deficit)	\$ 17,096,444	\$ 16,061,665	\$ 5,702,238	9,379,180	470,001
--	---------------	---------------	--------------	-----------	---------

(1)

Authorized 200,000,000 shares; issued and outstanding 78,773,736 & 65,881,122 & 53,760,471 at December 31st, 2013, 2012, and 2011, respectively. Authorized 100,000,000 shares; issued and outstanding 51,647,171 and 26,259,515 shares outstanding at December 31, 2010 and 2009, respectively.

Table of Contents

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)
Consolidated Statement of Operations

	Years Ended December 31,				
	2013	2012	2011	2010	2009
Operating expenses:					
Research and development	\$ 10,533,004	\$ 6,375,795	\$ 4,102,847	\$ 1,673,202	\$ 1,807,908
General and administrative	8,472,197	6,403,656	4,555,872	1,724,102	835,515
Total operating expenses	19,005,201	12,779,451	8,658,719	3,397,304	2,643,423
Operating loss	(19,005,201)	(12,779,451)	(8,658,719)	(3,397,304)	(2,643,423)
Other income (expense):					
Other income					383,000
Interest income	15,279	35,184	8,759	3,379	282
Interest expense	(129,902)	(71,726)	(12,676)	(564,443)	(255,737)
Modification of warrants	(764,769)				
Derivatives gain (loss)	(18,871,329)	17,479,674	(26,065,579)	(3,952,582)	
Other income (expense), net	(19,750,721)	17,443,132	(26,069,496)	(4,513,646)	127,545
Net income (loss)	\$ (38,755,922)	\$ 4,663,681	\$ (34,728,215)	\$ (7,910,950)	\$ (2,515,878)
Net income (loss) per share, basic	\$ (0.52)	\$ 0.07	\$ (0.67)	\$ (0.24)	\$ (0.10)
Net income (loss) per share, diluted	\$ (0.52)	\$ 0.06	\$ (0.67)	\$ (0.24)	\$ (0.10)
Weighted average number of common shares outstanding, basic	73,991,686	63,226,899	51,894,871	33,367,239	25,496,366
Weighted average number of common shares outstanding, diluted	73,991,686	71,919,419	51,894,871	33,367,239	25,496,366

Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form 10-K

We have derived our statements of operations data for the years ended December 31, 2009 and 2010 and our balance sheet data as of December 31, 2009, 2010 and 2011 from our audited financial statements which are not included in this Form 10-K. We have derived our statements of operations data for the years ended December 31, 2011, 2012, and 2013 and our balance sheet data as of December 31, 2012 and 2013 from our audited financial statements appearing elsewhere in this Annual Report on Form 10-K. Our audited financial information is prepared and presented in accordance with generally accepted accounting principles in the U.S. (U.S. GAAP).

Our selected consolidated financial data should be read together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form 10-K

Table of Contents

Supplementary Quarterly Financial Data (Unaudited)

	Quarter Ended			
	December 31, 2013	September 30, 2013	June 30, 2013	March 31, 2013
Operating expenses:				
Research and development	\$ 3,707,497	\$ 3,021,166	\$ 2,590,858	\$ 1,213,483
General and administrative	1,967,504	2,385,534	2,481,176	1,637,983
Total operating expenses	5,675,001	5,406,700	5,072,034	2,851,466
Operating loss	(5,675,001)	(5,406,700)	(5,072,034)	(2,851,466)
Other income (expense):				
Other income				
Interest income	2,215	4,153	6,331	2,580
Interest expense	(34,494)	(34,053)	(32,800)	(28,555)
Modification of warrants			(764,769)	
Derivatives gain (loss)			(8,422,513)	(10,448,816)
Other income (expense), net	(32,279)	(29,900)	(9,213,751)	(10,474,791)
Net income (loss)	\$ (5,707,280)	\$ (5,436,600)	\$ (14,285,785)	\$ (13,326,257)

	Quarter Ended			
	December 31, 2012	September 30, 2012	June 30, 2012	March 31, 2012
Operating expenses:				
Research and development	\$ 2,752,995	\$ 1,374,852	\$ 1,307,395	\$ 940,553
General and administrative	1,969,727	1,466,049	1,447,668	1,520,212
Total operating expenses	4,722,722	2,840,901	2,755,063	2,460,765
Operating loss	(4,722,722)	(2,840,901)	(2,755,063)	(2,460,765)
Other income (expense):				
Other income				
Interest income	7,342	13,061	12,344	2,437
Interest expense	(43,579)	(12,454)	(10,687)	(5,006)
Modification of warrants				
Derivatives gain (loss)	(3,956,979)	10,869,209	4,954,238	5,613,206

Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form 10-K

Other income (expense), net	(3,993,216)	10,869,816	4,955,895	5,610,637
-----------------------------	-------------	------------	-----------	-----------

Net income (loss)	\$ (8,715,938)	\$ 8,028,915	\$ 2,200,832	\$ 3,149,872
-------------------	----------------	--------------	--------------	--------------

Table of Contents

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

This discussion contains forward-looking statements that involve risks and uncertainties that could cause actual results or events to differ materially from those expressed or implied by such forward-looking statements as a result of many important factors, including those set forth in Part I of this Annual Report on Form 10-K under the caption "Risk Factors." Please see "Special Note Regarding Forward-Looking Statements" in Part I above. We do not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this Annual Report.

The discussion and analysis of our financial condition and results of operations are based on the Company's financial statements, which management has prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base estimates on historical experience and on various other factors that management believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

As the result of the October 2010 merger with InVivo Therapeutics Corporation and related transactions, InVivo Therapeutics Corporation was considered the accounting acquirer and therefore the financial results of InVivo Therapeutics Corporation are now considered the financial results of the Company on a historical and going-forward basis.

Overview

We develop novel biomaterial technologies for the treatment of spinal cord injuries and hydrogels for therapeutics delivery. Our proprietary technologies incorporate intellectual property that is licensed under an exclusive, world-wide license from Children's Medical Center Corporation ("CMCC") and the Massachusetts Institute of Technology ("MIT"), as well as intellectual property that has been developed internally in collaboration with our advisors and partners. At December 31, 2013, we were considered a "development stage enterprise" and will continue to be so until we commence commercial operations. A development stage enterprise is one in which planned principal operations have not commenced or, if its operations have commenced, there has been no significant revenue from operations. Development stage companies report cumulative costs from the date of inception of the enterprise.

Our development stage started on November 28, 2005 and continued through December 31, 2013. As of December 31, 2013, we have experienced total net losses since inception of approximately \$81,909,000. As a development stage enterprise, we expect to incur substantial operating losses in the future and are therefore dependent upon external financing, such as from equity and debt offerings, to finance our operations. Before we can derive revenue or cash inflows from the commercialization of any of our products, we will need to conduct clinical studies and obtain regulatory approval to commercialize our products.

Overall, we expect our R&D expenses to be substantial and to increase for the foreseeable future as we continue the development and clinical investigation of our current and future products. However, expenditures on R&D programs are subject to many uncertainties, including whether we develop our products with a partner or independently or acquire products. At this time, due to the uncertainties and inherent risks involved in our development stage business, we cannot estimate in a meaningful way the duration of, or the costs to complete, our R&D programs or whether, when or to what extent we will generate revenues or cash inflows from the commercialization and sale of any of our products.

Table of Contents

While we are currently focused on advancing our scaffold product, our future R&D expenses will depend on the determinations we make as to the scientific and clinical prospects of each product, as well as our ongoing assessment of the regulatory requirements and each product's commercial potential. In addition, we may make acquisitions of businesses, technologies or intellectual property rights that we believe would be necessary, useful or complementary to our current business. Any investment made in a potential acquisition could affect our results of operations and reduce our limited capital resources, and any issuance of equity securities in connection with a potential acquisition could be substantially dilutive to our stockholders.

There can be no assurance that we will be able to successfully develop or acquire any product, or that we will be able to recover our development or acquisition costs, whether upon commercialization of a developed product or otherwise. We cannot provide assurance that any of our programs under development or any acquired technologies or products will result in products that can be marketed or marketed profitably. If our development-stage programs or any acquired products or technologies do not result in commercially viable products, our results of operations could be materially adversely affected.

We were incorporated on April 2, 2003, under the name of Design Source, Inc. On October 26, 2010, we acquired the business of InVivo Therapeutics Corporation, which was founded in 2005, and continued the existing business operations of InVivo Therapeutics Corporation as our wholly-owned subsidiary. As a result of the merger and related transactions, InVivo Therapeutics Corporation was considered the accounting acquirer and therefore the historical financial results of InVivo Therapeutics Corporation are considered the financial results of the Company on a historical and going-forward basis.

Significant Events

Warrant Exchange Offer. Certain of our issued and outstanding warrants to purchase common stock issued in 2010 contained anti-dilution provisions. As a result, these warrants did not meet the requirements for classification as equity and were recorded as derivative warrant liabilities. In April 2013, we announced our offer to exchange the outstanding warrants containing these anti-dilution provisions for new warrants with the same terms except (i) the expiration date of the new warrants was extended two years and (ii) weighted average anti-dilution provisions were removed from the new warrants (the "Offer"). On May 17, 2013, we completed the Offer and exchanged an aggregate of 3,319,091 the warrants containing the anti-dilution provisions for new warrants to purchase an aggregate of 3,319,091 shares of our common stock.

Warrant Redemption. In addition, in May 2013, we called for the redemption of outstanding investor warrants issued in 2010 in accordance with the terms of those warrants. As a result, during the three months ended June 30, 2013, a total of 11,726,343 warrants were exercised, providing cash proceeds of \$15,984,304.

Changes in Executive Leadership. In December 2013, Steven F. McAllister was appointed as Interim Chief Financial Officer. In January 2014, Mark D. Perrin was appointed as Chief Executive Officer and also joined the Company's Board of Directors. In February 2014, we announced the hiring of Thomas R. Ulich, MD as our Chief Scientific Officer.

Critical Accounting Policies and Estimates

Our consolidated financial statements, which appear in Item 8 of this Annual Report on Form 10-K, have been prepared in accordance with accounting principles generally accepted in the United States, which require that the management make certain assumptions and estimates and, in connection therewith, adopt certain accounting policies. Our significant accounting policies are set forth in Note 2 to our consolidated financial statements. Of those policies, we believe that the policies

Table of Contents

discussed below may involve a higher degree of judgment and may be more critical to an accurate reflection of our financial condition and results of operations.

Share-Based Compensation

Stock options are generally granted with an exercise price at fair market value at the date of the grant. The stock options generally expire ten years from the date of grant. Stock option awards vest upon terms determined by the Company's Board of Directors.

We recognize compensation costs resulting from the issuance of stock-based awards to employees, non-employees and directors as an expense in the statement of operations over the service period based on a measurement of fair value for each stock-based award. The fair value of each option grant was estimated as of the date of grant using the Black-Scholes option-pricing model. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period. Due to our limited operating history and limited number of sales of our Common Stock, we estimated our volatility in consideration of a number of factors including the volatility of our stock as well as that of comparable public companies. We use historical data, as well as subsequent events occurring prior to the issuance of the consolidated financial statements, to estimate option exercise and employee termination within the valuation model. The expected term of options granted under the Company's stock plans is based on the average of the contractual term (generally 10 years) and the vesting period (generally 48 months) The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option.

The following assumptions were used to estimate the fair value of stock options granted using the Black-Scholes option pricing model:

	December 31,		
	2013	2012	2011
Risk-free interest rate	0.77 - 2.52%	0.62 - 1.23%	0.97 - 3.05%
Expected dividend yield	0%	0%	0%
Expected term (employee grants)	6.25	6.25	6.25
Expected volatility	102%	75%	49%
Derivative Instruments			

Prior to May 2013, certain of our issued and outstanding warrants to purchase Common Stock contained anti-dilution provisions. These warrants did not meet the requirements for classification as equity and were recorded as derivative warrant liabilities. We used valuation methods and assumptions that consider among other factors the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates consistent with those discussed in Share-Based Compensation above in estimating the fair value for the warrants considered to be derivative warrant liabilities. Such derivative warrant liabilities were initially recorded at fair value with subsequent changes in fair value charged (credited) to operations in each reporting period. The fair value of the derivative warrant liability was most sensitive to changes in the fair value of the underlying Common Stock and the estimated volatility of our Common Stock.

Research and Development and General and Administrative Expenses

Research and development expenses consist primarily of payroll and payments to contract research and development companies and payroll. General and administrative expenses consist primarily of payroll, rent and professional services.

Table of Contents

Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2013-11 Income Taxes (Topic 740) Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists that provides guidance on whether an uncertain tax position should be presented as a reduction to a deferred tax asset or as a separate liability. This guidance seeks to address diversity in practice. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. We do not expect the adoption of this ASU amendment to have any effect on the financial condition, results of operations or cash flows.

Results of Operations

Comparison of the years ended December 31, 2013 and 2012

Research and Development Expenses

Research and development expenses increased by \$4,157,000 to approximately \$10,533,000 for the year ended December 31, 2013 from approximately \$6,376,000 for the year ended December 31, 2012. The increase is primarily attributable to increased research and development activity and the resulting increase in compensation costs of \$1,447,000 due to both additional staffing and pay raises, \$1,693,000 related to stock option expense, increase in rent and facility costs of \$605,000, and higher pre-clinical testing costs of \$880,000.

General and Administrative Expenses

General and administrative expenses increased by \$2,068,000 to approximately \$8,472,000 for the year ended December 31, 2013 from approximately \$6,404,000 for the year ended December 31, 2012. The increase in expenses is primarily attributable to higher legal costs of \$1,179,000, an increase of \$391,000 in compensation costs related to staffing and pay increases, an increase of \$210,000 in stock compensation costs and an increase in rent and facilities costs of \$344,000. Partly offsetting these increases is a reduction in other spending of \$56,000.

Interest Expense

Interest expense increased by \$58,000 to approximately \$130,000 for the year ended December 31, 2013 from approximately \$72,000 for the year ended December 31, 2012. The increase in interest expense is due to an increase in borrowing under the loans payable.

Derivatives Gain (Loss)

Derivatives loss increased by approximately \$36,351,000 to a loss of approximately \$18,871,000 for the year ended December 31, 2013 from a gain of approximately \$17,480,000 for the year ended December 31, 2012. The increase in this non-cash loss during the year ended December 31, 2013 reflects the increase in the fair value of derivative warrant liability prior to reclassification to additional paid-in capital due primarily to the increase in the fair value of the underlying Common Stock.

Loss from Modification of Warrants

Loss from modification of warrants was \$765,000 for the year ended December 31, 2013. The charge is attributable to an increase in the fair value of warrants that resulted from the modification of the terms of warrants on May 17, 2013.

Table of Contents

Comparison of the years ended December 31, 2012 and 2011

Research and Development Expenses

Research and development expenses increased by \$2,273,000 to approximately \$6,376,000 for the year ended December 31, 2012 from approximately \$4,103,000 for the year ended December 31, 2011. The increase in expenses is primarily attributable to increased research and development activity and the resulting increase in compensation costs of \$1,245,000 due to both additional staffing and pay raises, \$765,000 of costs in 2012 for the manufacturing of scaffolding devices, increase in rent and facility costs of \$609,000, and increase in lab supplies of \$212,000, offset by a reduction in pre-clinical testing of \$861,000.

General and Administrative Expenses

General and administrative expenses increased by \$1,848,000 to approximately \$6,404,000 for the year ended December 31, 2012 from approximately \$4,556,000 for the year ended December 31, 2011. The increase in expenses is primarily attributable to an increase in compensation costs of \$534,000 due to additional staffing and pay raises, an increase of \$178,000 in legal costs, an increase of \$238,000 in recruiting and relocation costs, an increase of \$170,000 in travel and conference meeting costs, an increase of \$455,000 in stock compensation costs and an increase in rent and facilities costs of \$240,000.

Interest Expense

Interest expense increased by \$59,000 to approximately \$72,000 for the year ended December 31, 2012 from approximately \$13,000 for the year ended December 31, 2011. The increase in interest expense is due to an increase in borrowing under the loans payable.

Derivatives Gain (Loss)

Derivatives gain (loss) increased by approximately \$43,546,000 to a derivative gain of \$17,480,000 for the year ended December 31, 2012 from a derivative loss of \$26,066,000 for the year ended December 31, 2011. The increase in this non-cash gain for the year ended December 31, 2012 reflects the decrease in the fair value of derivative warrant liability due primarily to the decrease in the fair value of the underlying Common Stock.

Financial Condition, Liquidity and Capital Resources

Since inception, we have devoted substantially all of our efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. Accordingly, the Company is considered to be in the development stage.

Since inception, we have incurred negative cash flows from operations, and historically we have financed our operations primarily through the sale of equity-related securities. At December 31, 2013, the accumulated deficit was approximately \$81,909,000 and the stockholders' equity was approximately \$12,890,000.

At December 31, 2013, we had total current assets of \$14,602,000 and current liabilities of \$2,268,000 resulting in a working capital of \$12,334,000. At December 31, 2013, we had total assets of \$17,096,000 and total liabilities of \$4,207,000, resulting in a stockholders' equity of \$12,890,000.

Net cash used by operating activities for the year ended December 31, 2013 was approximately \$14,906,000. The operating loss used \$19,005,000, decreases in accounts payable and increases in accrued expenses provided \$18,000, non-cash stock share based compensation provided \$3,136,000 and depreciation and amortization provided \$741,000.

Table of Contents

Net cash used by investing activities for the year ended totaled \$749,000 for purchases of capital equipment.

Net cash provided by financing activities was approximately \$16,810,000 for the year ended December 31, 2013, due mainly to approximately \$15,952,000 proceeds from issuance of common stock and warrants. In addition, we received \$456,000 from the exercise of stock options and approximately \$402,000 from loans and notes, net of repayments.

The accompanying consolidated financial statements have been prepared on a basis that assumes that the Company will continue as a going concern and that contemplates the continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the normal course of business. We have incurred losses since inception in devoting substantially all of our efforts toward research and development and have an accumulated deficit of approximately \$81,909,000 at December 31, 2013. During the year ended December 31, 2013, we generated a net loss of approximately \$38,756,000, used approximately \$14,906,000 of cash in operations and we expect that we will continue to generate operating losses for the foreseeable future. At December 31, 2013, the consolidated cash balance was approximately \$13,980,000. We believe this cash balance is adequate to fund operations through October 2014.

We have incurred significant operating losses and negative cash flows since inception. We have not achieved profitability and may not be able to realize sufficient revenue to achieve or sustain profitability in the future. We do not expect to be profitable in the next several years, but rather expect to incur additional operating losses. We have limited liquidity and capital resources and must obtain significant additional capital resources in order to sustain our product development efforts, for acquisition of technologies and intellectual property rights, for preclinical and clinical testing of our anticipated products, pursuit of regulatory approvals, acquisition of capital equipment, laboratory and office facilities, establishment of production capabilities, for selling, general and administrative expenses and other working capital requirements. We have, in the past, successfully completed multiple rounds of financings, but, due to market conditions and other factors, including our development stage and our ability to continue as a going concern, we may be unable to raise the required capital in the future.

We intend to pursue opportunities to obtain additional financing in the future through equity and/or debt financings. We have filed with the SEC, and the SEC declared effective, a universal shelf registration statement which permits us to issue up to \$100 million worth of registered equity securities. Under this effective shelf registration, we have the flexibility to issue registered securities, from time to time, in one or more separate offerings or other transactions with the size, price and terms to be determined at the time of issuance. Registered securities issued using this shelf may be used to raise additional capital to fund our working capital and other corporate needs, for future acquisitions of assets, programs or businesses, and for other corporate purposes.

The source, timing and availability of any future financing will depend principally upon market conditions, interest rates and, more specifically, on our progress in our exploratory, preclinical and future clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate some or all of our research and product development programs, planned clinical trials, and our capital expenditures or to license our potential products or technologies to third parties.

Off Balance Sheet Arrangements

We have no off balance sheet arrangements that have or are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures, or capital resources.

Table of Contents**Contractual Obligations**

In the table below, we set forth our legally binding and enforceable contractual cash obligations at December 31, 2013:

Contractual Obligations	Total	Payments Due			More than 5 years
		Less than 1 year	1 - 3 years	3 - 5 years	
Long-term debt	\$ 1,920,000	\$ 1,137,778	\$ 782,222	\$	\$
Operating lease payments	6,058,132	1,202,585	3,806,127	1,049,420	
Capital lease (equipment)	2,799	2,799			
Total	\$ 7,980,931	\$ 1,205,384	\$ 4,943,904	\$ 1,831,642	\$

Commitments

See Note 17, "Commitments and Contingencies" in the Notes to Consolidated Financial Statements in Item 8 of this Annual Report on Form 10-K for information.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The following discussion about our market risk disclosures involves forward-looking statements. Actual results could differ materially from those discussed in the forward-looking statements. See "Special Note Regarding Forward-Looking Statements" above in Management's Discussion and Analysis of Financial Condition and Results of Operations. We are exposed to market risk related to changes in interest rates. We do not use derivative financial instruments for speculative or trading purposes.

Our interest-bearing assets, or interest-bearing portfolio, consist of cash and cash equivalents. The balance of our interest-bearing portfolio was approximately \$13,980,321, or 82%, of total assets at December 31, 2013 and \$12,825,090, or 80%, of total assets at December 31, 2012. Interest income earned on these assets was approximately \$15,279 in 2013 and \$35,184 in 2012. Our interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates. At December 31, 2013, our cash equivalents were primarily composed of money market accounts comprised of U.S. Treasury debt securities and repurchase agreements.

Table of Contents

Item 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Consolidated Financial Statements

	Page
<u>Report of Independent Registered Public Accounting Firm</u>	<u>36</u>
<u>Consolidated Balance Sheets</u>	<u>37</u>
<u>Consolidated Statements of Operations</u>	<u>38</u>
<u>Consolidated Statements of Changes in Stockholders' Equity (Deficit)</u>	<u>39</u>
<u>Consolidated Statements of Cash Flows</u>	<u>40</u>
<u>Notes to Consolidated Financial Statements</u>	<u>41</u>

Table of Contents

Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheets of InVivo Therapeutics Holdings Corp. as of December 31, 2013 and 2012, and the related consolidated statements of operations, changes stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2013 and for the period from November 28, 2005 (inception) to December 31, 2013. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of InVivo Therapeutics Holdings Corp. as of December 31, 2013 and 2012, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2013 and for the period from November 28, 2005 (inception) to December 31, 2013, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, has a significant accumulated deficit and has been unable to raise sufficient capital to fund its operations through the end of 2014. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), InVivo Therapeutics Holdings Corp.'s internal control over financial reporting as of December 31, 2013, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 Framework), and our report dated March 17, 2014 expressed an unqualified opinion on the effectiveness of InVivo Therapeutics Holdings Corp.'s internal control over financial reporting.

/s/ Wolf & Company, P.C.
Boston, Massachusetts
March 17, 2014

Table of Contents

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Consolidated Balance Sheets

	December 31,	
	2013	2012
ASSETS:		
Current assets:		
Cash and cash equivalents	\$ 13,980,321	\$ 12,825,090
Restricted cash	601,471	601,351
Prepaid expenses and other current assets	20,087	143,867
Total current assets	14,601,879	13,570,308
Property and equipment, net	2,337,210	2,311,942
Other assets	157,355	179,415
Total assets	\$ 17,096,444	\$ 16,061,665
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT):		
Current liabilities:		
Accounts payable	\$ 899,260	\$ 1,152,550
Note payable-current portion	73,987	
Capital lease payable-current portion	2,799	32,606
Derivative warrant liability		14,584,818
Accrued expenses	1,292,185	1,021,275
Total current liabilities	2,268,231	16,791,249
Loan payable	1,920,000	1,578,000
Note payable-less current portion	18,497	
Capital lease payable-less current portion		2,799
Total liabilities	4,206,728	18,372,048
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, \$0.00001 par value, authorized 200,000,000 shares; issued and outstanding 78,773,736 and 65,881,122 shares at December 31 2013 and 2012, respectively	788	659
Additional paid-in capital	94,798,231	40,842,339
Deficit accumulated during the development stage	(81,909,303)	(43,153,381)
Total stockholders' equity (deficit)	12,889,716	(2,310,383)
Total liabilities and stockholders' equity (deficit)	\$ 17,096,444	\$ 16,061,665

See report of independent registered public accounting firm and notes to the consolidated financial statements.

Table of Contents

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Consolidated Statements of Operations

	Years Ended December 31,			Period from
	2013	2012	2011	November 28, 2005 (inception) to December 31, 2013
Operating expenses:				
Research and development	\$ 10,533,004	\$ 6,375,795	\$ 4,102,847	\$ 25,792,633
General and administrative	8,472,197	6,403,656	4,555,872	23,127,390
Total operating expenses	19,005,201	12,779,451	8,658,719	48,920,023
Operating loss	(19,005,201)	(12,779,451)	(8,658,719)	(48,920,023)
Other income (expense):				
Other income				383,000
Interest income	15,279	35,184	8,759	70,512
Interest expense	(129,902)	(71,726)	(12,676)	(1,267,959)
Modification of warrants	(764,769)			(764,769)
Derivatives gain (loss)	(18,871,329)	17,479,674	(26,065,579)	(31,409,816)
Other income (expense), net	(19,750,721)	17,443,132	(26,069,496)	(32,989,032)
Net income (loss)	\$ (38,755,922)	\$ 4,663,681	\$ (34,728,215)	\$ (81,909,055)
Net income (loss) per share, basic	\$ (0.52)	\$ 0.07	\$ (0.67)	\$ (2.04)
Net income (loss) per share, diluted	\$ (0.52)	\$ 0.06	\$ (0.67)	\$ (2.04)
Weighted average number of common shares outstanding, basic	73,991,686	63,226,899	51,894,871	40,121,647

Weighted average number of common shares outstanding, diluted	73,991,686	71,919,419	51,894,871	40,121,647
--	------------	------------	------------	------------

See report of independent registered public accounting firm and notes to the consolidated financial statements.

Table of Contents

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Consolidated Statements of Changes in Stockholders' Equity (Deficit)

	Common Stock		Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance on inception date, November 28, 2005		\$	\$	\$	\$
Issuance of founders stock	24,787,080	248		(248)	
Share-based compensation expense			18,347		18,347
Net loss				(1,097,702)	(1,097,702)
Balance as of December 31, 2007	24,787,080	248	18,347	(1,097,950)	(1,079,355)
Share-based compensation expense			24,526		24,526
Net loss				(1,564,069)	(1,564,069)
Balance as of December 31, 2008	24,787,080	248	42,873	(2,662,019)	(2,618,898)
Share-based compensation expense			171,059		171,059
Conversion of convertible notes payable and accrued interest	1,472,435	15	1,344,351		1,344,366
Net loss				(2,515,878)	(2,515,878)
Balance as of December 31, 2009	26,259,515	263	1,558,283	(5,177,897)	(3,619,351)
Share-based compensation expense			664,908		664,908
Issuance of common stock in March 2010	1,095,258	10	999,990		1,000,000
Conversion of convertible notes payable and accrued interest	3,792,417	38	3,328,090		3,328,128
Issuance of common stock in reverse merger	6,999,981	70	(70)		
Beneficial conversion feature on notes payable			272,762		272,762
Issuance of common stock in private placement, net of stock issuance costs of \$2,072,117 and non stock issuance costs of \$5,369,570	12,995,403	130	3,907,274		3,907,404
Conversion of convertible bridge notes in conjunction with the private placement	504,597	5	504,592		504,597
Net loss				(7,910,950)	(7,910,950)
Balance as of December 31, 2010	51,647,171	516	11,235,829	(13,088,847)	(1,852,502)
Share-based compensation expense			921,512		921,512
Issuance of common stock in private placement	980,392	10	1,999,990		2,000,000
Issuance of common stock for services	215,000	2	209,448		209,450
Issuance of common stock upon exercise of warrants	734,329	7	988,367		988,374
Issuance of common stock upon exercise of stock options	143,731	2	10,433		10,435
Issuance of common stock to 401(k) plan	39,848	1	41,661		41,662
Fair value of warrants issued for services			10,051		10,051
Fair value of derivative warrant liability reclassified to additional paid-in capital			1,239,539		1,239,539
Net loss				(34,728,215)	(34,728,215)
Balance as of December 31, 2011	53,760,471	538	16,656,830	(47,817,062)	(31,159,694)
Share-based compensation expense			1,232,959		1,232,959
Issuance of common stock in public offering	9,523,810	95	18,154,948		18,155,043
Issuance of common stock for services	15,000		24,750		24,750
Issuance of common stock upon exercise of warrants	1,779,716	18	1,129,077		1,129,095
Issuance of common stock upon exercise of stock options	755,020	8	111,597		111,605
Issuance of common stock to 401(k) plan	47,105		91,524		91,524

Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form 10-K

Fair value of warrants issued for services			31,916		31,916
Fair value of derivative warrant liability reclassified to additional paid-in capital			3,408,738		3,408,738
Net income				4,663,681	4,663,681
Balance as of December 31, 2012	65,881,122	659	40,842,339	(43,153,381)	(2,310,383)
Share-based compensation expense			3,135,646		3,135,646
Issuance of common stock upon exercise of warrants	12,224,846	122	15,951,985		15,952,107
Issuance of common stock upon exercise of stock options	588,884	6	455,544		455,550
Issuance of common stock to 401(k) plan	78,884	1	191,801		191,802
Fair value of derivative warrant liability reclassified to additional paid-in capital			33,456,147		33,456,147
Incremental fair value from warrant modification			764,769		764,769
Net loss				(38,755,922)	(38,755,922)
Balance as of December 31, 2013	78,773,736	\$ 788	\$ 94,798,231	\$ (81,909,303)	\$ 12,889,716

See report of independent registered public accounting firm and notes to the consolidated financial statements.

Table of Contents

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Consolidated Statements of Cash Flows

	Years Ended December 31,			Period from November 28, 2005 (inception) to December 31, 2013
	2013	2012	2011	2013
Cash flows from operating activities:				
Net income (loss)	\$ (38,755,922)	\$ 4,663,681	\$ (34,728,215)	\$ (81,909,055)
Adjustments to reconcile net income (loss) to net cash used in operating activities:				
Depreciation and amortization expense	740,692	366,893	144,662	1,345,212
Non-cash derivative (gain) losses	18,871,329	(17,479,674)	26,065,579	31,409,816
Non-cash interest expense		21,870		984,704
Non-cash loss from modification of warrants	764,769			764,769
Common stock issued to 401(k) plan	191,802	91,524	41,662	324,988
Common stock issued for services		24,750	209,451	234,201
Share-based compensation expense	3,135,646	1,232,959	921,512	6,168,957
Changes in operating assets and liabilities:				
Restricted cash	(120)	(53,468)	(547,883)	(601,471)
Prepaid expenses and other current assets	123,780	(60,575)	(12,805)	(30,766)
Other assets	4,560		(125,000)	(195,440)
Accounts payable	(253,290)	585,355	230,250	899,260
Accrued interest payable				(15,256)
Accrued expenses	270,910	402,906	370,822	1,292,185
Net cash used in operating activities	(14,905,844)	(10,203,779)	(7,429,965)	(39,327,896)
Cash flows from investing activities:				
Purchases of property and equipment	(748,460)	(2,140,853)	(278,923)	(3,520,021)
Net cash used in investing activities	(748,460)	(2,140,853)	(278,923)	(3,520,021)
Cash flows from financing activities:				
Proceeds from issuance of note payable	149,768			149,768
Repayment of note payable	(57,284)			(57,284)
Proceeds from issuance of convertible notes payable				4,181,000
Proceeds from convertible bridge notes				500,000
Principal payments on capital lease obligation	(32,606)	(33,361)	(24,774)	(90,741)
Proceeds from loans payable	342,000	1,747,000	151,733	2,240,733
Repayment of loans payable		(303,372)	(17,361)	(320,733)
Proceeds from issuance of common stock and warrants	16,407,657	19,395,743	2,998,808	50,225,495
Net cash provided by financing activities	16,809,535	20,806,010	3,108,406	56,828,238
Increase (Decrease) in cash and cash equivalents	1,155,231	8,461,378	(4,600,482)	13,980,321
Cash and cash equivalents at beginning of period	12,825,090	4,363,712	8,964,194	
Cash and cash equivalents at end of period	\$ 13,980,321	\$ 12,825,090	\$ 4,363,712	\$ 13,980,321

Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form 10-K

Supplemental disclosure of cash flow information and non-cash transactions:

Cash paid for interest	\$	125,342	\$	49,862	\$	8,530	\$	281,251
------------------------	----	---------	----	--------	----	-------	----	---------

Conversion of convertible notes payable and accrued interest into common stock	\$		\$		\$		\$	4,672,484
--	----	--	----	--	----	--	----	-----------

Conversion of convertible bridge note payable and accrued interest into common stock	\$		\$		\$		\$	504,597
--	----	--	----	--	----	--	----	---------

Asset acquired through capital lease obligation	\$		\$		\$	93,540	\$	93,540
---	----	--	----	--	----	--------	----	--------

Beneficial conversion feature on convertible and bridge notes payable	\$		\$		\$		\$	134,410
---	----	--	----	--	----	--	----	---------

Fair value of warrants issued with bridge notes payable	\$		\$		\$		\$	178,726
---	----	--	----	--	----	--	----	---------

Fair value of warrants issued in connection with loan agreement	\$		\$	31,916	\$	10,051	\$	41,967
---	----	--	----	--------	----	--------	----	--------

Issuance of founders shares	\$		\$		\$		\$	248
-----------------------------	----	--	----	--	----	--	----	-----

Reclassification of derivative warrant liability to additional paid-in capital	\$	33,456,147	\$	3,408,738	\$	1,239,539	\$	38,104,424
--	----	------------	----	-----------	----	-----------	----	------------

See report of independent registered public accounting firm and notes to the consolidated financial statements.

Table of Contents

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements

**Years Ended December 31, 2013, 2012 and 2011, and the Period from
November 28, 2005 (Inception) through December 31, 2013**

1. NATURE OF OPERATIONS AND GOING CONCERN

Business

InVivo Therapeutics Corporation ("InVivo") was incorporated on November 28, 2005 under the laws of the State of Delaware. We develop novel biomaterial technologies for the treatment of spinal cord injuries and hydrogels for therapeutics delivery. Our proprietary technologies incorporate intellectual property licensed under an exclusive, world-wide license from Children's Medical Center Corporation ("CMCC") and the Massachusetts Institute of Technology ("MIT"), and intellectual property that has been developed internally, including in collaboration with our advisors and partners.

Since its inception, InVivo has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. Accordingly, InVivo is considered to be in the development stage.

Going Concern

The accompanying financial statements have been prepared on a basis that assumes that the Company will continue as a going concern and that contemplates the continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company has incurred losses since inception in devoting substantially all of its efforts toward research and development and has an accumulated loss of \$81,909,055 at December 31, 2013. During the year ended December 31, 2013, the Company generated a net loss of \$38,755,922, used cash in operations of \$14,905,844 and the Company expects that it will continue to generate operating losses for the foreseeable future. The Company believes that its cash balance at December 31, 2013 of \$13,980,321 is adequate to fund operations at budgeted levels through October of 2014. The Company's ability to execute its operating plan beyond October of 2014 depends on its ability to obtain additional funding via the sale of equity and/or debt securities, a strategic transaction or otherwise. The Company plans to continue to actively pursue financing alternatives, but there can be no assurance that it will obtain the necessary funding. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Reverse Merger

On October 26, 2010 InVivo completed a reverse merger transaction (the "Merger") with InVivo Therapeutics Holdings Corp. (formerly Design Source, Inc.) ("ITHC"), a publicly traded company incorporated under the laws of the State of Nevada. InVivo became a wholly owned subsidiary of ITHC, which continues to operate the business of InVivo. As part of the Merger, ITHC issued 31,147,190 shares of its Common Stock to the holders of InVivo common stock on October 26, 2010 in exchange for the 2,261,862 outstanding common shares of InVivo and also issued 500,000 shares to its legal counsel in consideration for legal services provided. All share and per share amounts presented in these consolidated financial statements have been retroactively restated to reflect the 13.7706 to 1 exchange ratio of InVivo shares for ITHC shares in the Merger. Immediately prior to the Merger, ITHC had 6,999,981 shares of Common Stock outstanding.

Table of Contents

**InVivo Therapeutics Holdings Corp.
(A Development Stage Company)**

Notes to Consolidated Financial Statements (Continued)

**Years Ended December 31, 2013, 2012 and 2011, and the Period from
November 28, 2005 (Inception) through December 31, 2013**

1. NATURE OF OPERATIONS AND GOING CONCERN (Continued)

The Merger was accounted for as a "reverse merger," and InVivo is deemed to be the accounting acquirer. The Merger was recorded as a reverse recapitalization, equivalent to the issuance of common stock by InVivo for the net monetary assets of ITHC accompanied by a recapitalization. At the date of the Merger, the 6,999,981 outstanding ITHC shares were reflected as an issuance of InVivo common stock to the prior shareholders of ITHC. ITHC had no net monetary assets as of the Merger so this issuance was recorded as a reclassification between additional paid-in capital and par value of Common Stock.

The historical consolidated financial statements are those of InVivo as the accounting acquirer. The post-merger combination of ITHC and InVivo is referred to throughout these notes to consolidated financial statements as the "Company." Subsequent to the Merger, the Company completed three closings as part of a private placement.

2. SIGNIFICANT ACCOUNTING POLICIES

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

Use of estimates

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

Principles of consolidation

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

Cash and cash equivalents

The Company considers only those investments which are highly liquid, readily convertible to cash, and that mature within three months from date of purchase to be cash equivalents. Marketable investments are those with original maturities in excess of three months.

At December 31, 2013 and 2012, cash equivalents were comprised of money market funds. The Company had no marketable investments at December 31, 2013 and 2012.

Table of Contents

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

**Years Ended December 31, 2013, 2012 and 2011, and the Period from
November 28, 2005 (Inception) through December 31, 2013**

2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

Cash and cash equivalents consist of the following:

	December 31,	
	2013	2012
Cash on deposit	\$ 219,378	\$ 209,380
Money market fund	13,760,943	12,615,710
Total cash and cash equivalents	\$ 13,980,321	\$ 12,825,090

Restricted cash

Restricted cash of \$601,471 represents a \$290,106 security deposit related to the Company's credit card account, and a \$311,365 standby letter of credit in favor of a landlord (see Note 17).

Financial instruments

The carrying amounts reported in the consolidated balance sheet for cash and cash equivalents and accounts payable approximate fair value based on the short-term nature of these instruments. The carrying value of note and loans payable approximates their fair value due to the market terms.

Property and equipment

Property and equipment are carried at cost. Depreciation expense is provided over the estimated useful lives of the assets using the straight-line method. A summary of the estimated useful lives is as follows:

Classification	Estimated Useful Life
Computer hardware	5 years
Software	3 years
Office furniture and equipment	5 years
Research and lab equipment	5 years
Leasehold improvements	Remaining Life of Lease

Depreciation expense for the years ended December 31, 2013, 2012, and 2011 was \$723,192, \$349,393, and \$132,162 respectively. Maintenance and repairs are charged to expense as incurred, while any additions or improvements are capitalized.

Research and development expenses

Costs incurred for research and development are expensed as incurred.

Table of Contents

**InVivo Therapeutics Holdings Corp.
(A Development Stage Company)**

Notes to Consolidated Financial Statements (Continued)

**Years Ended December 31, 2013, 2012 and 2011, and the Period from
November 28, 2005 (Inception) through December 31, 2013**

2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

Concentrations of credit risk

The Company has no off-balance-sheet concentration of credit risk such as foreign exchange contracts, option contracts or other hedging arrangements. The Company may from time to time have cash in banks in excess of FDIC insurance limits.

Segment information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision making group, in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and manages its business as principally one operating segment, which is developing and commercializing biopolymer scaffolding devices for the treatment of spinal cord injuries. As of December 31, 2013 and 2012, all of the Company's assets were located in the United States.

Income taxes

For federal and state income taxes, deferred tax assets and liabilities are recognized based upon temporary differences between the financial statement and the tax basis of assets and liabilities. Deferred income taxes are based upon prescribed rates and enacted laws applicable to periods in which differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that some portion or all of the deferred tax assets will not be realized. Accordingly, the Company provides a valuation allowance, if necessary, to reduce deferred tax assets to amounts that are realizable. Tax positions taken or expected to be taken in the course of preparing the Company's tax returns are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authority.

Tax positions not deemed to meet a more-likely-than-not threshold would be recorded as a tax expense in the current year. There were no uncertain tax positions that require accrual or disclosure to the financial statements as of December 31, 2013 or 2012. Tax years subsequent to 2009 remain open to examination by U.S. federal and state tax authorities.

Impairment of long-lived assets

The Company continually monitors events and changes in circumstances that could indicate that carrying amounts of long-lived assets may not be recoverable. An impairment loss is recognized when expected cash flows are less than an asset's carrying value. Accordingly, when indicators of impairment are present, the Company evaluates the carrying value of such assets in relation to the operating performance and future undiscounted cash flows of the underlying assets. The Company's policy is to record an impairment loss when it is determined that the carrying value of the asset may not be recoverable. No impairment charges were recorded for the years ended December 31, 2013, 2012 and 2011.

Table of Contents

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

**Years Ended December 31, 2013, 2012 and 2011, and the Period from
November 28, 2005 (Inception) through December 31, 2013**

2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

Share-based payments

The Company recognizes compensation costs resulting from the issuance of stock-based awards to employees, non-employees and directors as an expense in the statement of operations over the service period based on a measurement of fair value for each stock-based award. The fair value of each option grant is estimated as of the date of grant using the Black-Scholes option-pricing model. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period. Due to its limited operating history, limited number of sales of its Common Stock and limited history of its shares being publicly traded, the Company estimates its volatility in consideration of a number of factors including the volatility of comparable public companies.

Derivative instruments

The Company generally does not use derivative instruments to hedge exposures to cash-flow or market risks; however, certain warrants to purchase Common Stock that do not meet the requirements for classification as equity are classified as liabilities. In such instances, net-cash settlement is assumed for financial reporting purposes, even when the terms of the underlying contracts do not provide for a net-cash settlement. Such financial instruments are initially recorded at fair value with subsequent changes in fair value charged (credited) to operations in each reporting period. If these instruments subsequently meet the requirements for classification as equity, the Company reclassifies the fair value to equity.

Net income (loss) per common share

Basic net income (loss) per share of Common Stock has been computed by dividing net income (loss) by the weighted average number of shares outstanding during the period. Diluted net income per share of Common Stock has been computed by dividing net income by the weighted average number of shares outstanding plus the dilutive effect, if any, of outstanding stock options, warrants and convertible securities. Diluted net loss per share of Common Stock has been computed by dividing the net loss for the period by the weighted average number of shares of Common Stock outstanding during such period. In a net loss period, options, warrants and convertible securities are anti-dilutive and therefore excluded from diluted loss per share calculations.

Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2013-11 Income Taxes (Topic 740) Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists that provides guidance on whether an uncertain tax position should be presented as a reduction to a deferred tax asset or as a separate liability. This guidance seeks to address diversity in practice. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The Company does not expect the adoption of this ASU amendment to have any effect on the financial condition, results of operations or cash flows.

Table of Contents

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

**Years Ended December 31, 2013, 2012 and 2011, and the Period from
November 28, 2005 (Inception) through December 31, 2013**

3. PROPERTY AND EQUIPMENT

Property and equipment, net consisted of the following:

	2013	2012
Computer software and hardware	\$ 559,934	\$ 362,352
Research and lab equipment	1,881,656	1,448,226
Leasehold improvements	381,225	298,222
Office Equipment	790,746	756,301
Less accumulated depreciation and amortization	(1,276,351)	(553,159)

Property and equipment, net \$ 2,337,210 \$ 2,311,942

4. INTANGIBLE ASSETS

Intangible assets, included in Other Assets, consist of patent licensing fees paid to license intellectual property (see Note 16. The Company is amortizing the license fee to research and development expense over its 15-year term.

	2013	2012
Patent licensing fee	\$ 200,000	\$ 200,000
Accumulated amortization	(68,861)	(51,361)
	\$ 131,139	\$ 148,639

For the years ended December 31, 2013, 2012, and 2011 the amortization expense was \$17,500, \$17,500, and \$12,500. Amortization expense in each of the next five years is expected to be approximately \$17,000 per year.

5. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	December 31,	
	2013	2012
Accrued bonus	\$ 565,489	\$
Accrued payroll	101,283	224,596
Deferred rent payable	553,285	310,076
Accrued vacation	23,188	

Other accrued expenses	48,940	486,603
------------------------	--------	---------

\$ 1,292,185 \$ 1,021,275

Table of Contents

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

**Years Ended December 31, 2013, 2012 and 2011, and the Period from
November 28, 2005 (Inception) through December 31, 2013**

6. NOTE PAYABLE

In May 2013, the Company entered into a contract for the purchase of an Enterprise Resource Planning ("ERP") system for approximately \$150,000. The total cost for the ERP system including interest is approximately \$159,000 with an implicit interest rate of approximately 6%.

Pursuant to the terms of this non-cancelable purchase agreement ("Note payable") in effect at December 31, 2013, the future minimum principal payments are as follows:

Year Ended December 31,	
2014	\$ 73,987
2015	18,497
Total	\$ 92,484

In the third quarter of 2013, the Company decided to abandon the implementation of the ERP system. As such, the purchase was fully expensed in 2013. The Company will reserve the right to implement the ERP system at a future date.

7. FAIR VALUES OF ASSETS AND LIABILITIES

The Company groups its assets and liabilities generally measured at fair value in three levels, based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value.

Level 1 Valuation is based on quoted prices in active markets for identical assets or liabilities. Level 1 assets and liabilities generally include debt and equity securities that are traded in an active exchange market. Valuations are obtained from readily available pricing sources for market transactions involving identical assets or liabilities.

Level 2 Valuation is based on observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Valuation is based on unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation.

The Company uses valuation methods and assumptions that consider among other factors the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants considered to be derivative instruments.

Table of Contents

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

**Years Ended December 31, 2013, 2012 and 2011, and the Period from
November 28, 2005 (Inception) through December 31, 2013**

7. FAIR VALUES OF ASSETS AND LIABILITIES (Continued)

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

	December 31, 2012			Fair Value
	Level 1	Level 2	Level 3	
Liabilities:				
Derivative warrant liability	\$	\$ 14,584,818	\$	\$ 14,584,818

There were no assets or liabilities measured at fair value on a recurring basis at December 31, 2013.

8. CAPITAL LEASE PAYABLE

In February 2011, the Company entered into a capital lease agreement under which the Company leased certain laboratory equipment. Capital lease obligation consisted of the following:

	December 31,	
	2013	2012
Capital lease payable	\$ 2,799	\$ 35,405
Less: current portion	(2,799)	(32,606)
	\$	\$ 2,799

The total value of the laboratory equipment acquired under this capital lease agreement was \$124,151 including a down payment of approximately \$31,000. The capital lease is payable in monthly installments of \$2,812 payable over thirty six months with the final payment due in January 2014. For the years ended December 31, 2013 and 2012, interest expense recorded on the capital lease was \$1,133 and \$3,189, respectively. For the years ended December 31, 2013, 2012, and 2011, depreciation expense on the assets under capital lease was \$24,831, \$24,831 and \$22,761, respectively. The net book value at December 31, 2013 and 2012 amounted to \$51,730 and \$76,559, respectively.

9. LOAN PAYABLE

In October 2012, the Company entered into a loan agreement with the Massachusetts Development Finance Agency ("MassDev") from the Commonwealth of Massachusetts's Emerging Technology fund. The loan agreement provides the Company with a \$2,000,000 line of credit, with \$200,000 to be used for working capital purposes and the remainder of which is to be used for the purchase of capital equipment. The annual interest rate is fixed at 6.5% with interest payments only commencing on November 1, 2012 for the first thirty months and then equal interest and principal payments over the next fifty-four months with the final maturity on October 5, 2019. Based on the \$1,920,000 balance outstanding as of December 31, 2013, equal monthly principal payments of \$35,556 will be due commencing on May 1, 2015. Therefore, for the years ending December 31, 2015, 2016, 2017, 2018, and 2019 principal payments of approximately \$284,444, \$426,667, \$426,667, \$426,667, and \$355,555 respectively, will be due. In September 2012, the Company was assessed commitment fees

Table of Contents

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

**Years Ended December 31, 2013, 2012 and 2011, and the Period from
November 28, 2005 (Inception) through December 31, 2013**

9. LOAN PAYABLE (Continued)

totaling \$15,000, which was charged to interest expense. In October 2012 as part of the commitment fee, the Company issued MassDev a warrant for the purchase of 36,145 shares of Common Stock. The warrant has a seven year term and is exercisable at \$1.66 per share. The fair value of the warrant was determined to be \$31,916 and was recorded as a deferred financing cost and is being amortized to interest expense over a seven year period commencing in October 2012. Amortization of the deferred financing cost for the year ended December 31, 2013 and 2012 was \$4,560 and \$1,140 respectively and was included in interest expense. The equipment line of credit is secured by substantially all the assets of the Company excluding intellectual property. During 2013, the Company drew on the line and received proceeds of \$342,000, for capital equipment. Interest expense related to this loan was \$119,817 for the year ended December 31, 2013 and \$14,794 for the year ended December, 31 2012.

In June 2011, the Company entered into a loan agreement with a bank. The loan agreement had provided the Company with a \$1,000,000 line of credit for the purchase of capital equipment. The annual interest rate was the greater of 6.75% or 3.50% above the Prime Rate. Borrowings were repayable in equal monthly installments over a thirty six month period. The Company was assessed commitment fees totaling \$10,000 and issued the bank a warrant for the purchase of 16,071 shares of Common Stock. The warrant has a seven year term and is exercisable at \$1.40 per share. The fair value of the warrant was determined to be approximately \$10,000 and was recorded as a deferred financing cost that was being amortized to interest expense over the life of the loan. Under the terms of the MassDev loan disclosed above, in October 2012 the Company repaid the outstanding balance of \$134,372 due to the bank and wrote off the remaining deferred financing costs. Amortization of deferred interest on this loan for the years ended December 31, 2012 and 2011 was \$6,219 and \$4,146, respectively, and was included in interest expense. Interest expense related to the loan payable to the bank was \$16,428 and \$8,334 for the years ended December 31, 2012 and 2011, respectively.

At December 31, loans payable consist of the following:

	December 31,	
	2013	2012
Equipment Loan	\$ 1,920,000	\$ 1,578,000
Less: current portion		
	\$ 1,920,000	\$ 1,578,000

10. INCOME TAXES

No provision or benefit for federal or state income taxes has been recorded, as the Company has incurred a net loss for all of the periods presented, and the Company has provided a full valuation allowance against its deferred tax assets.

At December 31, 2013, the Company had Federal and Massachusetts net operating loss carryforwards of approximately \$41,615,000 and \$35,656,000, respectively, of which federal carryforwards will expire in varying amounts beginning in 2026. Massachusetts net operating losses began to expire in 2011. Utilization of net operating losses may be subject to substantial annual

Table of Contents

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

**Years Ended December 31, 2013, 2012 and 2011, and the Period from
November 28, 2005 (Inception) through December 31, 2013**

10. INCOME TAXES (Continued)

limitations due to the "change in ownership" provisions of the Internal Revenue Code, and similar state provisions. The annual limitations may result in the expiration of net operating losses before utilization. The Company also had research and development tax credit carryforwards at December 31, 2013 of approximately \$680,000 which will begin to expire in 2021 unless previously utilized.

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

	December 31,	
	2013	2012
Net operating loss carryforward	\$ 16,031,911	\$ 10,329,617
Research and development credit carryforward	624,902	329,584
Stock-based compensation	2,411,438	1,090,746
Depreciation and amortization	(148,802)	(81,305)
Accrued expenses	448,563	
Charitable contributions	111,776	72,693
Subtotal	19,479,788	11,741,335
Valuation allowance	(19,479,788)	(11,741,335)
Net deferred taxes	\$	\$

The Company has maintained a full valuation allowance against its deferred tax assets in all periods presented. A valuation allowance is required to be recorded when it is more likely than not that some portion or all of the net deferred tax assets will not be realized. Since the Company cannot be assured of generating taxable income and thereby realizing the net deferred tax assets, a full valuation allowance has been provided. In the years ended December 31, 2013 and 2012, the valuation allowance increased by \$7,738,000 and \$4,778,000, respectively.

The Company has no uncertain tax positions at December 31, 2013 and 2012 that would affect its effective tax rate. The Company does not anticipate a significant change in the amount of uncertain tax positions over the next twelve months. Since the Company is in a loss carryforward position, the Company is generally subject to US federal and state income tax examinations by tax authorities for all years for which a loss carryforward is available.

Table of Contents

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

**Years Ended December 31, 2013, 2012 and 2011, and the Period from
November 28, 2005 (Inception) through December 31, 2013**

10. INCOME TAXES (Continued)

Income tax benefits computed using the federal statutory income tax rate differs from the Company's effective tax rate primarily due to the following:

	December 31,		
	2013	2012	2011
Statutory rate	(34.0)%	34.0%	(34.0)%
State taxes, net of benefit	(2.6)%	(14.2)%	(1.4)%
Permanent differences:			
Derivative losses	17.1%	(127.4)%	25.7%
Other	0.0%	(1.9)%	0.2%
R&D tax credit	(0.4)%	7.0%	(0.2)%
Increase in valuation reserve	19.9%	102.5%	9.7%
Effective tax rate	0.0%	0.0%	0.0%

11. COMMON STOCK

The Company has authorized 200,000,000 shares of Common Stock, \$0.00001 par value per share, of which 78,773,736, shares were issued and outstanding as of December 31, 2013, and 65,881,122 shares were issued and outstanding as of December 31, 2012.

During the year ended December 31, 2013, the Company issued 588,884 shares of Common Stock upon the exercise of stock options and received cash proceeds of approximately \$455,550.

During the year ended December 31, 2013, the Company issued 12,224,846 shares of Common Stock upon the exercise of warrants, including warrants to purchase 627,036 shares of Common Stock exercised through cashless exercise provisions and warrants to purchase 11,813,334 shares of Common Stock exercised for cash, providing cash proceeds of approximately \$15,952,000.

During the year ended December 31, 2013, the Company issued 78,884 shares of Common Stock with a fair value of \$191,802 to the Company's 401(k) plan as a matching contribution.

In February 2012, the Company completed a public offering of Common Stock and issued 9,523,810 shares of Common Stock at a purchase price of \$2.10 per common share. The offering raised gross proceeds of approximately \$20,000,000 and the Company received net proceeds of \$18,155,000 after deducting underwriter discounts and offering expenses.

During 2012, the Company issued 15,000 unregistered shares of Common Stock with a fair value of approximately \$25,000 to an investor relations firm in exchange for services provided.

During the year ended December 31, 2012, the Company issued 755,020 shares of Common Stock upon the exercise of stock options and received cash proceeds of approximately \$112,000.

Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form 10-K

During the year ended December 31, 2012, the Company issued 1,779,716 shares of Common Stock upon the exercise of warrants, including warrants to purchase 1,865,670 shares of Common Stock

Table of Contents

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

**Years Ended December 31, 2013, 2012 and 2011, and the Period from
November 28, 2005 (Inception) through December 31, 2013**

11. COMMON STOCK (Continued)

exercised through cashless exercise provisions and warrants to purchase 852,946 shares of Common Stock exercised for cash, providing cash proceeds of \$1,129,000.

In December 2011, the Company completed a private placement with an investor that raised \$2,000,000 of net proceeds. In this transaction the Company issued 980,392 shares of unregistered common stock and a warrant to purchase 343,137 shares exercisable at \$03.06 per share with a five year term. The warrant was recorded as a debit and credit to additional paid-in capital.

During 2011, the Company issued 143,731 shares of Common Stock upon the exercise of stock options and received cash proceeds of approximately \$10,000.

During 2011, the Company issued 215,000 unregistered shares with a fair value of approximately \$198,000 to an investor relations firms in exchange for services provided.

In 2011, the Company issued 39,848 shares with a fair value of approximately \$42,000 to the Company's 401(k) plan as a matching contribution.

During the fourth quarter of 2011, the Company issued 734,329 shares upon the exercise of warrants and received cash proceeds of approximately \$988,000.

Common Stock Reserves

As of December 31, 2013, the Company had the following reserves established for the future issuance of Common Stock as follows:

Reserves for the exercise of warrants	3,283,134
Reserves for the exercise of stock options	12,979,197
Total Reserves	16,262,331

12. DERIVATIVE INSTRUMENTS

Certain warrants issued to investors and the placement agent warrants in the fourth quarter of 2010 had provisions that included anti-dilution protection and, under certain conditions, granted the right to the holder to require the Company to repurchase the warrant. Accordingly through March 2013, these warrants were accounted for as derivative liabilities. In the quarter ended March 31, 2013, \$476,426 was reclassified from Derivative warrant liability to Additional paid-in capital related to warrants exercised. In May 2013, the Company called for the redemption of all the outstanding investor warrants and during the quarter ended June 30, 2013, all such warrants, for a total of 11,726,343 warrants, were exercised and the fair value of \$25,241,401 was reclassified from Derivative warrant liability to Additional paid-in capital. There were no derivative instruments subsequent to June 30, 2013.

On May 17, 2013, the Company completed its offer to exchange certain of its outstanding warrants to purchase shares of the Company's common stock (the "Eligible Warrants") for new warrants (the "New Warrants") with the same terms except (i) the expiration date of the New

Warrants was extended

Table of Contents

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

**Years Ended December 31, 2013, 2012 and 2011, and the Period from
November 28, 2005 (Inception) through December 31, 2013**

12. DERIVATIVE INSTRUMENTS (Continued)

two years and (ii) weighted average anti-dilution provisions were removed from the New Warrants (the "Offer"). The Eligible Warrants consisted of (i) warrants to purchase common stock dated October 26, 2010, issued in connection with the closing of a merger (the "Merger Warrants") and (ii) warrants to purchase common stock issued to the placement agent as compensation for services in connection with each closing of a private placement which occurred on October 26, 2010, November 10, 2010 and December 3, 2010 (the "Placement Agent Warrants"). In connection with the Offer, Merger Warrants to purchase 255,000 shares of the Company's common stock and Placement Agent Warrants to purchase 3,064,091 shares of the Company's common stock were tendered and accepted for exchange for New Warrants to purchase an aggregate of 3,319,091 shares of the Company's common stock. Due to the modification of the terms, the Eligible Warrants were revalued prior to modification and immediately after modification as of May 17, 2013. This resulted in an incremental fair value immediately after the modification and the Derivative warrant liability was increased by \$764,769 and a corresponding non-cash charge was recorded in Other expense as Loss from modification of warrants. Since the New Warrants are not accounted for as derivative liabilities, the fair value of these warrants after modification of \$7,738,320 was reclassified from Derivative warrant liability to Additional paid-in capital.

The Company used the Black-Scholes option pricing model and assumptions that consider among other factors the fair value of the underlying stock, risk-free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants considered to be derivative instruments. The fair value of these derivative instruments at December 31, 2013 and 2012 was \$0 and \$14,584,818, respectively and was included as a derivative warrant liability, a current liability. Changes in fair value of the derivative financial instruments are recognized currently in the Statement of Operations as a derivatives gain or loss. The warrant derivative gains (losses) are non-cash income (expenses) and for the years ended December 31, 2013, 2012, and 2011 were \$(18,871,329), \$17,479,674, and \$(26,065,579), respectively, were included in other income (expense) in the consolidated statements of operations.

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

	2012	2011
Risk free interest rate	0.32 - 0.35%	0.52 - 0.58%
Expected dividend yield	0%	0%
Contractual term	2.7 - 2.9 years	3.7 - 3.9 years
Expected volatility	73%	79%

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

Table of Contents

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

**Years Ended December 31, 2013, 2012 and 2011, and the Period from
November 28, 2005 (Inception) through December 31, 2013**

12. DERIVATIVE INSTRUMENTS (Continued)

The table below presents the changes in derivative warrant liability during the years ended December 31, 2013, 2012, and 2011:

	Year Ended December 31,		
	2013	2012	2011
Balance at beginning of year	\$ 14,584,818	\$ 35,473,230	\$ 10,647,190
Increase (decrease) in the fair value of the warrants	18,871,329	(17,479,674)	26,065,579
Reduction in derivative liability due to exercise of warrants	(33,456,147)	(3,408,738)	(1,239,539)
Balance at end of year	\$ 14,584,818	\$ 35,473,230	

13. STOCK OPTIONS

In 2007, the Company adopted the 2007 Employee, Director and Consultant Stock Plan (the "2007 Plan"). Pursuant to the 2007 Plan, the Company's Board of Directors (or committees and/or executive officers delegated by the Board of Directors) may grant incentive and nonqualified stock options to the Company's employees, officers, directors, consultants and advisors. As of December 31, 2013, there were options to purchase an aggregate of 2,198,050 shares of Common Stock outstanding under the 2007 Plan and no shares available for future grants under the 2007 Plan.

On October 26, 2010, the Company's Board of Directors adopted and the Company's shareholders subsequently approved the 2010 Equity Incentive Plan, (the "2010 Plan"). The 2010 Plan provides for grants of incentive stock options to employees and nonqualified stock options and restricted Common Stock to employees, consultants and non-employee directors of the Company. As of December 31, 2013, the number of shares authorized for issuance under the 2010 Plan, as amended, was 11,000,000 shares. As of December 31, 2013, there were options to purchase an aggregate of 5,857,472 shares of Common Stock outstanding under the 2010 Plan and 4,923,675 shares available for future grants under the 2010 Plan. Options issued under the 2007 Plan and the 2010 Plan (collectively the "Plans") are exercisable for up to 10 years from the date of issuance.

Share-based compensation

For stock options issued and outstanding for the years ended December 31, 2013, 2012 and 2011, the Company recorded non-cash, stock-based compensation expense of \$3,135,646, \$1,232,959 and \$921,512, respectively, net of forfeitures.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model that uses the assumptions noted in the following table. Due to its limited operating history and limited number of sales of its Common Stock, the Company estimated its volatility in consideration of a number of factors including the volatility of comparable public companies. The Company uses historical data, as well as subsequent events occurring prior to the issuance of the financial statements, to estimate option exercises and employee terminations within the valuation model. The expected term of options granted under the Plans, all of which qualify as "plain vanilla," is based on the average of the contractual term (10 years) and the vesting period (generally 48 months). For non-employee options, the expected term is the contractual term. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option.

Table of Contents

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

**Years Ended December 31, 2013, 2012 and 2011, and the Period from
November 28, 2005 (Inception) through December 31, 2013**

13. STOCK OPTIONS (Continued)

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

	December 31,		
	2013	2012	2011
Risk-free interest rate	0.77 - 2.52%	0.62 - 1.23%	0.97 - 3.05%
Expected dividend yield	0%	0%	0%
Expected term (employee grants)	6.25	6.25	6.25
Expected volatility	102%	75%	49%

A summary of option activity as of December 31, 2013 and changes for the year then ended are presented below:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2012	8,648,268	\$ 1.29		
Granted	3,035,000	\$ 2.23		
Forfeited	(2,902,584)	\$ 1.63		
Exercised	(725,162)	\$ 0.88		
 Outstanding at December 31, 2013	 8,055,522	 \$ 1.56	 7.55	 \$ 6,704,149
 Vested at December 31, 2013	 3,661,215	 \$ 0.91	 5.50	 \$ 5,035,700

The weighted average grant-date fair value of options granted during years ended December 31, 2013, 2012, and 2011 was \$2.04, \$1.28, and \$1.14 per share, respectively. The total fair value of options that vested in years ended December 31, 2013, 2012, and 2011 was \$1,985,034, \$1,186,098 and \$1,324,325 respectively. As of December 31, 2013, there was approximately \$6,277,267 of total unrecognized compensation expense, related to non-vested share-based option compensation arrangements. The unrecognized compensation expense is estimated to be recognized over a period of 3.09 years at December 31, 2013.

In September 2011, the Company granted 80,000 shares of Common Stock under the 2010 Plan to a consultant as a restricted stock award with 30,000 shares vesting upon FDA clearance of an Investigational Device Exemption to permit the commencement of a human clinical trial and 50,000 shares vesting upon FDA approval of the Company's biopolymer scaffolding device to treat spinal cord injuries. The Company had previously determined that the vesting of the 30,000 shares was probable and the fair value of these shares at \$23,400 was being amortized over an eight month period from September 2011 through April 2012. In March of 2012, the contract with the consultant was terminated and the consultant had no vested right to the restricted stock, so accordingly, the \$11,700 of expense previously recorded was reversed in 2012.

Table of Contents

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

**Years Ended December 31, 2013, 2012 and 2011, and the Period from
November 28, 2005 (Inception) through December 31, 2013**

14. WARRANTS

The following presents information about warrants to purchase Common Stock issued and outstanding at December 31, 2013:

Year Issued	Classification	Number of Warrants	Exercise Price	Date of Expiration
2010	Equity	1,533,163	\$ 1.40	10/26/2017 - 12/3/2017
2010	Equity	1,354,618	\$ 1.00	9/26/2015 - 12/3/2015
2011	Equity	16,071	\$ 1.40	6/17/2018
2011	Equity	343,137	\$ 3.06	12/21/2016
2012	Equity	36,145	\$ 1.66	10/5/2019

Total		3,283,134		
-------	--	-----------	--	--

Weighted average exercise price			\$ 1.41	
---------------------------------	--	--	---------	--

Weighted average life in years				3.62
--------------------------------	--	--	--	------

15. EMPLOYEE BENEFIT PLAN

In November 2006, the Company adopted a 401(k) plan (the "Plan") covering all employees. Employees must be 21 years of age in order to participate in the Plan. Under the Plan, the Company has the option to make matching contributions. For the years ended December 31, 2013, 2012 and 2011, the Company made matching contributions in the form of shares of common stock. For the years ended December 31, 2013, 2012, and 2011, the Company issued 78,884, 47,105, and 39,848 shares of common stock, respectively, and related fair values of \$191,802, \$91,524, and \$41,662, respectively, were recorded as expense in the Statement of Operations.

16. INTELLECTUAL PROPERTY LICENSE

The Company has a world-wide exclusive license (the "CMCC License") for patents co-owned by Massachusetts Institute of Technology and Harvard's Children's Hospital initially covering the use of biopolymers to treat spinal cord injuries, and to promote the survival and proliferation of human stem cells in the spinal cord. During 2011, the Company obtained additional rights for use in the field of peripheral nerve injuries. The CMCC License has a 15-year term, or as long as the life of the last expiring patent right, whichever is longer, unless terminated earlier by the licensor. In connection with the CMCC License, the Company paid an initial \$75,000 licensing fee and is required to pay certain annual maintenance fees, milestone payments and royalties. During 2011, the Company paid \$75,000 to expand the license and at December 31, 2011, accrued \$50,000 for a milestone payment. License fees are capitalized and all costs associated with maintenance of the CMCC License are expensed as incurred (see Note 4).

17. COMMITMENTS AND CONTINGENCIES

On November 30, 2011 and as amended on September 17, 2012, the Company entered into a commercial lease for 26,150 square feet of office, laboratory and manufacturing space in Cambridge,

Table of Contents

**InVivo Therapeutics Holdings Corp.
(A Development Stage Company)**

Notes to Consolidated Financial Statements (Continued)

**Years Ended December 31, 2013, 2012 and 2011, and the Period from
November 28, 2005 (Inception) through December 31, 2013**

17. COMMITMENTS AND CONTINGENCIES (Continued)

Massachusetts ("Cambridge Lease"). The term of this lease is six years and three months, with one five-year extension option. The terms of the lease requires a standby letter of credit, as amended, in the amount of \$311,365 (see Note 2).

The Cambridge Lease contains rent holidays and rent escalation clauses. The Company recognizes rent expense on a straight-line basis over the lease term and record the difference between the amount charged to expense and the rent paid as a deferred rent liability. As of December 31, 2013, the amount of deferred rent liability is \$553,285 and is included in Accrued expenses.

It is the Company's policy to assess whether improvements made to the space rented under operating leases should be accounted for as lessor or lessee assets. If the landlord/lessor makes the improvements and presents us with the finished space on a "turnkey" basis, we view the assets as being lessor assets. When the Company does the remodeling work and receives an allowance that may or may not cover all the costs, the Company makes a judgment as to the classification between lessor and lessee assets. The Company considers an asset to be a lessor asset if all of the following criteria are met:

the lease specifically requires the lessee to make the improvement,

the improvement is fairly generic,

the improvement increases the fair value of the property to the lessor, and

the useful life of the improvement is longer than our lease term.

If any of the above criteria are not met, the Company considers the assets to be lessee assets, which are recorded as leasehold improvements in the balance sheet and payments received from the lessor to fund any portion of the cost of lessee assets are accounted for as lease incentives. Assets considered to be lessor assets are not reflected in the Company's Consolidated Balance Sheets. To the extent that the Company paid for such lessor assets and was not reimbursed through construction allowances, such net payments are recorded as leasehold improvements, which are amortized to rent expense over the lease term. As of December 31, 2013, such leasehold improvements totaled \$381,225.

Pursuant to the terms of the non-cancelable lease agreements in effect at December 31, 2013, the future minimum rent commitments are as follows:

Year Ended December 31,	
2014	1,202,585
2015	1,242,559
2016	1,268,708
2017	1,294,860
2018	1,049,420
Total	\$ 6,058,132

Table of Contents

InVivo Therapeutics Holdings Corp.
(A Development Stage Company)

Notes to Consolidated Financial Statements (Continued)

**Years Ended December 31, 2013, 2012 and 2011, and the Period from
November 28, 2005 (Inception) through December 31, 2013**

17. COMMITMENTS AND CONTINGENCIES (Continued)

Total rent expense for the years ended December 31, 2013, 2012, and 2011, including month-to-month leases, was \$1,125,000, \$758,000, and \$357,000, respectively.

On September 4, 2013, the Company entered into a legal settlement agreement for approximately \$286,000, in connection with the settlement of outstanding litigation, which has been included in the deferred rent liability and the benefit will be amortized over the remainder of the lease term.

Litigation

The Company has certain claims and pending legal proceedings in the ordinary course of business. In the opinion of management, such proceedings are not expected to have a material adverse effect on the Company's financial position, results of operations and cash flows.

In November 2013, we filed a lawsuit against Francis Reynolds, the Company's former Chairman, Chief Executive Officer and Chief Financial Officer, in Middlesex Superior Court, Middlesex County, Massachusetts (InVivo Therapeutics Holdings Corp. v. Reynolds, Civil Action No. 13-5004). The complaint alleges breaches of fiduciary duties, breach of contract, conversion, misappropriation of corporate assets, unjust enrichment, corporate waste, and seeks money damages and an accounting. The lawsuit involves approximately \$500,000 worth of personal and/or exorbitant expenses that the Company alleges Mr. Reynolds inappropriately caused the Company to pay while he was serving as the Company's Chief Executive Officer, Chief Financial Officer, President and Chairman of the Board of Directors. On December 6, 2013, Mr. Reynolds answered the complaint, and filed counterclaims against the Company and its Board of Directors. The counterclaims allege two counts of breach of contract, two counts of breach of the covenant of good faith and fair-dealing, and tortious interference with a contract, and seek monetary damages and a declaratory judgment. The counterclaims involve Mr. Reynolds's allegations that the Company and the Board interfered with the performance of his duties under the terms of his employment agreement, and that Mr. Reynolds was entitled to additional shares upon the exercise of certain stock options. On January 9, 2014, the Company and directors named in the counterclaims filed their answer. We expect discovery to begin soon. No judgments or rulings are pending at this early stage. We do not believe that the pending actions will materially impact the financial condition of the Company.

18. INSURANCE CLAIM

During the year ended December 31, 2013, the Company received insurance proceeds of approximately \$1,100,000 from the settlement of a business interruption claim that covered the disruption of the Company's operations at its facility in Cambridge, MA caused by water damage that occurred in November 2012. The insurance settlement reimbursed the Company for costs incurred as a result of the disruption is included as reduction of Research and Development Expense in the Consolidated Statement of Operations for the year ended December 31, 2013.

Table of Contents

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Our Disclosure Controls

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that material information required to be disclosed in our periodic reports filed under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, our chief executive officer and our chief financial officer, to allow timely decisions regarding required disclosure. As of the end of the period covered by this Annual Report on Form 10-K, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13(a)-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2013, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurances regarding the reliability of financial reporting and the preparation of our consolidated financial statements in accordance with U.S. generally accepted accounting principles, or GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate.

With the participation our chief executive officer and our chief financial officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2013 based on the framework in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 Framework) ("COSO"). Based upon our assessment and the COSO criteria, management concluded that our internal control over financial reporting was effective as of December 31, 2013.

Limitations on Effectiveness of Controls and Procedures

Our management, including our chief executive officer and our chief financial officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include, but are not limited to, the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future

Table of Contents

events and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Changes in Internal Controls over Financial Reporting

During the fiscal quarter ended December 31, 2013, there have been no changes in our internal control over financial reporting that have materially affected or are reasonably likely to materially affect our internal controls over financial reporting.

Independent Public Accounting Firm's Report on Internal Control over Financial Reporting

The independent registered public accounting firm that audited our consolidated financial statements included in this Annual Report on Form 10-K has issued its report on the effectiveness of our internal control over financial reporting. This report appears below.

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited InVivo Therapeutics Holdings Corp.'s (the "Company") internal control over financial reporting as of December 31, 2013, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 Framework). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (a) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (b) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (c) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, InVivo Therapeutics Holdings Corp. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 Framework).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of InVivo Therapeutics Holdings Corp. as of December 31, 2013 and 2012, and the related consolidated statements of operations, changes stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2013 and for the period from November 28, 2005 (inception) to December 31, 2013, and our report dated March 17, 2014, expressed an unqualified opinion on those consolidated financial statements and contained an explanatory paragraph about the entity's ability to continue as a going concern.

/s/ Wolf & Company, P.C.

Boston, Massachusetts

March 17, 2014

Table of Contents

Item 9B. OTHER INFORMATION

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required under this item is incorporated herein by reference to the information regarding directors, executive officers and corporate governance included in our proxy statement for our 2014 Annual Meeting of Stockholders.

Item 11. EXECUTIVE COMPENSATION

The information required under this item is incorporated herein by reference to the information regarding executive compensation included in our proxy statement for our 2014 Annual Meeting of Stockholders.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required under this item is incorporated herein by reference to the information regarding security ownership of certain beneficial owners and management and related stockholder matters included in our proxy statement for our 2014 Annual Meeting of Stockholders.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required under this item is incorporated herein by reference to the information regarding certain relationships and related transactions and director independence included in our proxy statement for our 2014 Annual Meeting of Stockholders.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required under this item is incorporated herein by reference to the information regarding principal accounting fees and services included in our proxy statement for our 2014 Annual Meeting of Stockholders.

Table of Contents

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Financial Statements.

The financial statements listed in the Index to Consolidated Financial Statements appearing in Item 8 are filed as part of this report.

Financial Statement Schedules.

All financial statement schedules have been omitted as they are either not required, not applicable, or the information is otherwise included.

Exhibits.

The exhibits listed in the Exhibit Index immediately preceding the exhibits are filed as part of this report.

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INVIVO THERAPEUTICS HOLDINGS CORP.

Date: March 17, 2014

By: /s/ STEVEN F. MCALLISTER

Name: Steven F. McAllister
 Title: *Interim Chief Financial Officer*

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
<p><u>/s/ MARK D. PERRIN</u> Mark D. Perrin</p>	<p>Chief Executive Officer (Principal Executive Officer), Director</p>	<p>March 17, 2014</p>
<p><u>/s/ STEVEN F. MCALLISTER</u> Steven F. McAllister</p>	<p>Interim Chief Financial Officer (Principal Financial Officer)</p>	<p>March 17, 2014</p>
<p><u>/s/ JOHN A. MCCARTHY, JR.</u> John A. McCarthy, Jr.</p>	<p>Non-Executive Chairman of the Board, Director</p>	<p>March 17, 2014</p>
<p><u>/s/ KENNETH DIPIETRO</u> Kenneth DiPietro</p>	<p>Director</p>	<p>March 17, 2014</p>
<p><u>/s/ RICHARD J. ROBERTS</u> Richard J. Roberts</p>	<p>Director</p>	<p>March 17, 2014</p>

Table of Contents

EXHIBIT INDEX

- 2.1 Agreement and Plan of Merger, dated October 4, 2010, by and between Design Source, Inc. and InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 2.2 to the Company's Current Report on Form 8-K, as filed with the SEC on October 6, 2010).
- 2.2 Agreement and Plan of Merger and Reorganization, dated as of October 26, 2010, by and among InVivo Therapeutics Holdings Corp. (f/k/a Design Source, Inc.), a Nevada corporation, InVivo Therapeutics Acquisition Corp., a Delaware corporation and InVivo Therapeutics Corporation, a Delaware corporation (incorporated by reference from Exhibit 2.1 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
- 3.1 Articles of Incorporation of InVivo Therapeutics Holdings Corp., as amended (incorporated by reference from Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011, as filed with the SEC on November 14, 2011).
- 3.2 Amended and Restated Bylaws of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on April 24, 2012).
- 4.1 Form of Bridge Warrant of InVivo Therapeutics Corporation (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
- 4.2 Form of Investor Warrant of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 4.3 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
- 4.3(i) Form of Warrant of InVivo Therapeutics Holdings Corp. (\$1.00 exercise price) issued to Placement Agent (incorporated by reference from Exhibit 4.2 to the Company's Current Report on Form 8-K, as filed with the SEC on December 9, 2010).
- 4.3(ii) Form of Warrant of InVivo Therapeutics Holdings Corp. (\$1.40 exercise price) issued to Placement Agent (incorporated by reference from Exhibit 4.3 to the Company's Current Report on Form 8-K, as filed with the SEC on December 9, 2010).
- 4.4 Form of Warrant of InVivo Therapeutics Holdings Corp. issued to Bridge Lenders (incorporated by reference from Exhibit 4.5 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
- 4.5 Warrant dated June 17, 2011 issued to Square 1 Bank (incorporated by reference from Exhibit 4.7 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011, as filed with the SEC on March 15, 2012).
- 4.6 Specimen Common Stock Certificate (incorporated by reference from Exhibit 4.8 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2011, as filed with the SEC on March 15, 2012).
- 4.7 Warrant dated October 5, 2012 issued to Massachusetts Development Finance Agency (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on October 9, 2012).

Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form 10-K

Table of Contents

- 4.8 Form of New Warrant issued on May 17, 2013 in exchange for Merger Warrants (incorporated by reference from Exhibit (a)(1)(D)(1) to the Company's Tender Offer Statement on Schedule TO (File No. 005-85686), as filed with the SEC on April 8, 2013).
- 4.9 Form of New Warrant issued on May 17, 2013 in exchange for Placement Agent Warrants (incorporated by reference from Exhibit (a)(1)(D)(3) to the Company's Tender Offer Statement on Schedule TO (File No. 005-85686), as filed with the SEC on April 8, 2013)
- 10.1 Form of Securities Purchase Agreement between InVivo Therapeutics Corporation and the Bridge Lenders (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
- 10.2 Form of Subscription Agreement, by and between InVivo Therapeutics Holdings Corp. and the investors in the offering (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on December 9, 2010).
- 10.3 Form of Registration Rights Agreement, by and between InVivo Therapeutics Holdings Corp. and the investors in the offering (incorporated by reference from Exhibit 10.4 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
- 10.4 Split-Off Agreement, by and among InVivo Therapeutics Holdings Corp., DSource Split Corp., Peter Reichard, Lawrence Reichard and Peter Coker (incorporated by reference from Exhibit 10.5 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
- 10.5 General Release Agreement, dated as of October 26, 2010, by and among InVivo Therapeutics Corp., DSource Split Corp., Peter Reichard, Lawrence Reichard and Peter Coker (incorporated by reference from Exhibit 10.6 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
- 10.6* Amended and Restated Executive Employment Agreement by and between InVivo Therapeutics Holdings Corp. and Frank Reynolds, dated March 5, 2012 (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on March 8, 2012).
- 10.7* InVivo Therapeutics Corp. 2007 Employee, Director and Consultant Stock Plan (incorporated by reference from Exhibit 10.9 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
- 10.8(i)* Form of Incentive Stock Option Agreement by and between InVivo Therapeutics Corp. and participants under the 2007 Employee, Director and Consultant Stock Plan (incorporated by reference from Exhibit 10.11(i) to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
- 10.8(ii)* Form of Non-Qualified Stock Option Agreement by and between InVivo Therapeutics Corp. and participants under the 2007 Employee, Director and Consultant Stock Plan (incorporated by reference from Exhibit 10.11(ii) to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
- 10.9* InVivo Therapeutics Holdings Corp. 2010 Equity Incentive Plan, as amended (incorporated by reference to Appendix A to the Company's Schedule 14A Proxy Statement, as filed with the SEC on April 19, 2013).
- 10.10(i)* Form of Incentive Stock Option Agreement by and between InVivo Therapeutics Holdings Corp. and participants under the 2010 Equity Incentive Plan (incorporated by reference from Exhibit 10.12(i) to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010, as filed with the SEC on March 24, 2011).

Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form 10-K

Table of Contents

- 10.10(ii)* Form of Non-Qualified Stock Option Agreement by and between InVivo Therapeutics Holdings Corp. and participants under the 2010 Equity Incentive Plan (incorporated by reference from Exhibit 10.12(ii) to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010, as filed with the SEC on March 24, 2011).
- 10.11 Form of Scientific Advisory Board Agreement entered into by InVivo Therapeutics Corp. (incorporated by reference from Exhibit 10.13 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
- 10.12 Exclusive License Agreement dated July 2007 between InVivo Therapeutics Corporation and Children's Medical Center Corporation (incorporated by reference from Exhibit 10.1 to Amendment No. 2 to the Company's Quarterly Report on Form 10-Q/A for the quarter ended March 31, 2011, as filed with the SEC on July 18, 2011).
- 10.13 Amendment One to the Exclusive License, dated May 12, 2011, by and between Children's Medical Center Corporation and InVivo Therapeutics Corporation (incorporated by reference from Exhibit 10.22 to the Amendment No. 4 to the Company's Registration Statement on Form S-1/A (File No. 333-171998), as filed with the SEC on July 19, 2011).
- 10.14 Finder's Fee Letter Agreement dated August 18, 2010, between InVivo Therapeutics Corporation and Placement Agent (incorporated by reference from Exhibit 10.3 to the Company's Current Report on Form 8-K, as filed with the SEC on December 9, 2010).
- 10.15 Placement Agency Agreement dated October 4, 2010, between InVivo Therapeutics Corp. and Placement Agent (incorporated by reference from Exhibit 10.4 to the Company's Current Report on Form 8-K, as filed with the SEC on December 9, 2010).
- 10.16 Finder's Agreement dated October 26, 2010, between InVivo Therapeutics Corp. and Placement Agent (incorporated by reference from Exhibit 10.5 to the Company's Current Report on Form 8-K, as filed with the SEC on December 9, 2010).
- 10.17 Master Services Agreement dated October 26, 2010, between InVivo Therapeutics Corp. and Placement Agent (incorporated by reference from Exhibit 10.6 to the Company's Current Report on Form 8-K, as filed with the SEC on December 9, 2010).
- 10.18 Form of Indemnification Agreement (for directors and officers) (incorporated by reference from Exhibit 10.19 to the Company's Registration Statement on Form S-1 (File No. 333-171998), as filed with the SEC on February 1, 2011).
- 10.19 Lease Agreement, dated November 30, 2011, between InVivo Therapeutics Corporation and RB Kendall Fee, LLC (incorporated by reference from Exhibit 10.25 to the Company's Registration Statement on Form S-1 (File No. 333-178584), as filed with the SEC on December 16, 2011).
- 10.20 Lease Guaranty, dated November 30, 2011, by InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 10.26 to the Company's Registration Statement on Form S-1 (File No. 333-178584), as filed with the SEC on December 16, 2011).
- 10.21 First Amendment of Lease between InVivo Therapeutics Corporation and RB Kendall Fee, LLC, dated September 17, 2012 (incorporated by reference from Exhibit 10.31 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2012, as filed with the SEC on March 12, 2013).
- 10.22 Securities Purchase Agreement, dated December 21, 2011, by and between the Company and Ingenieria E Inversiones Ltda. (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on December 22, 2011).

Edgar Filing: INVIVO THERAPEUTICS HOLDINGS CORP. - Form 10-K

Table of Contents

- 10.23 Common Stock Purchase Warrant dated December 21, 2011 and issued by the Company to Ingenieria E Inversiones Ltda. (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on December 22, 2011).
 - 10.24* InVivo Therapeutics Holdings Corp. Annual Cash Bonus Plan for Executive Officers (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on March 8, 2012).
 - 10.25 Promissory Note dated October 5, 2012 in favor of Massachusetts Development Finance Agency (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on October 9, 2012).
 - 10.26* Employment Agreement, dated as of August 22, 2013, between the Company and Michael J. Astrue.
 - 10.27* Employment Agreement, dated as of September 16, 2013, between the Company and Gregory D. Perry.
 - 10.28* Employment Agreement, dated as of December 23, 2013, between the Company and Mark D. Perrin.
 - 10.29* Employment Agreement, dated as of December 31, 2013, between the Company and Steven F. McAllister.
 - 21 Subsidiaries of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 21.1 to the Company's Current Report on Form 8-K, as filed with the SEC on November 1, 2010).
 - 23.1 Consent of Wolf & Company, P.C.
 - 31.1 Certification by the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
 - 31.2 Certification by the Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
 - 32.1 Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
 - 32.2 Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
 - 101.INS XBRL Instance Document
 - 101.SCH XBRL Taxonomy Extension Schema Document
 - 101.CAL XBRL Taxonomy Calculation Linkbase Document
 - 101.DEF XBRL Taxonomy Extension Definition Linkbase Document
 - 101.LAB XBRL Taxonomy Label Linkbase Document
 - 101.PRE XBRL Taxonomy Presentation Linkbase Document
-

*

Management contract or compensatory plan or arrangement filed in response to Item 15(a)(3) of Form 10-K.