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

FORM 10-K

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2014

☐ **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	**36-4528166**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One Kendall Square, Suite B14402, Cambridge, Massachusetts	**02139**
(Address of principal executive offices)	(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: 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 ☐ (Do not check if a smaller reporting company)	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 of the registrant as of June 30, 2014 was $97,155,701, based on a per share price of $1.04, the closing price of the registrant's common stock on the OTCQB on June 30, 2014.

As of March 5, 2015, the number of shares outstanding of the registrant's common stock, $0.00001 par value per share, was 102,410,850

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2015 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2014.

INVIVO THERAPEUTICS HOLDINGS CORP.
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2014

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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 and chronic spinal cord injury, the sufficiency of our existing capital resources for continuing operations in 2015, the safety, feasibility, and clinical effectiveness of our Neuro-Spinal Scaffold, our pilot clinical study of our Neuro-Spinal Scaffold and its related clinical development, and our ability to develop collaborations and partnerships to support our business plan. 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 Neuro-Spinal Scaffold and our Bioengineered Neural Tissue, which is comprised of our Neuro-Spinal Scaffold plus neural stem cells;
- 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 and licensing arrangements;
- 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.

Item 1. BUSINESS

Overview

We are a research and clinical-stage biomaterials and biotechnology company with a focus on treatment of spinal cord injuries. Our proprietary technologies incorporate intellectual property licensed under an exclusive, world-wide license from Boston Children's Hospital ("BCH") and the Massachusetts Institute of Technology ("MIT"), and intellectual property that has been developed internally, including in collaboration with our advisors and partners. We intend to leverage our platform technology to develop our novel Neuro-Spinal Scaffold, an investigational bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord contusion and is intended to treat acute spinal cord injury, or SCI. We believe our Neuro-Spinal Scaffold will be the foundation of effective therapy for both acute and chronic SCI, and we are continually evaluating other technologies and therapeutics that may be complementary and that offer the potential to bring us closer to our goal of redefining the life of the SCI patient.

Market Opportunity

Our clinical program is intended to address the lack of successful treatments for SCIs. The current management of acute SCI is a surgical approach consisting of spine stabilization and a decompression procedure of uncertain value.. Our mission is to redefine the life of the SCI patient. We are developing treatment options intended to provide meaningful improvement in patient outcomes following SCI. Our approach to treating SCIs is based on our investigational Neuro-Spinal Scaffold, which we believe is the only SCI therapy in development focused solely on treating SCI directly at the epicenter of the injury.

We believe the market opportunity for our Neuro-Spinal Scaffold and our technology is significant. It is estimated that approximately 276,000 people are currently living in the United States with paralysis due to spinal cord injury, and approximately 12,500 individuals in the United States will become fully or partially paralyzed each year. SCI can lead to permanent paralysis, sensory impairment, and autonomic, bowel, bladder, and sexual dysfunction.

Since 1973, the National Spinal Cord Injury Statistical Center ("NSCISC") at the University of Alabama has been commissioned by the U.S. government to maintain a national database of spinal cord injury statistics. The financial impact of spinal cord injuries, as reported by the NSCISC, is substantial. Direct costs, which include hospital and medical expenses, modification of the home, and personal assistance, are highest in the first year after injury. According to the fact sheet published by NSCISC titled "Spinal Cord Injury—Facts and Figures at a Glance" in conjunction with its 2014 Annual Report, (i) during the first year, average "cost of care" ranges from $342,112 to $1,048,259, depending on the severity of the injury, (ii) the net present value ("NPV") to maintain a quadriplegic injured at age 25 for life is $4,651,158, and (iii) the NPV to maintain a paraplegic injured at age 25 for life is $2,274,396. These costs place a tremendous financial burden on families, insurance providers, and government agencies. Moreover, despite such a significant financial investment, the patient often remains disabled for life because current medical interventions address only the symptoms of SCI rather than the underlying neurological cause. We believe our approach could represent an important advance in the treatment of SCIs.

Our Products

We currently have a clinical development program for acute SCI and a pre-clinical development program for chronic SCI.

Neuro-Spinal Scaffold

Our leading product is our Neuro-Spinal Scaffold, an investigational bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord contusion. The Neuro-Spinal Scaffold is surgically implanted at the epicenter of the wound and acts as a physical substrate for nerve sprouting. Appositional healing to spare spinal cord tissue, decrease post-traumatic cyst formation and decreased spinal cord tissue pressure have been demonstrated in preclinical models of spinal cord contusion injury . The Neuro-Spinal Scaffold is composed of two biocompatible and bioresorbable polymers:

- Poly lactic-*co*-glycolic acid (PLGA), a polymer that is widely used in resorbable sutures and provides the biocompatible support for Neuro-Spinal Scaffold; and

- Poly-L-Lysine (PLL), a positively charged polymer commonly used to coat surfaces in order to promote cellular attachment .

These two polymers are cast to form a highly porous scaffold that is conducive to cellular attachment and neurite outgrowth. The Neuro-Spinal Scaffold is intended to provide structural support and an environment supportive of cell survival and/or growth, and the device will degrade over several months. Surgical implantation of the Neuro-Spinal Scaffold is intended to mitigate tissue damage resulting from some of the critical pathophysiological events that occurs during the acute phase of SCI, such as increases in tissue pressure, hemorrhaging, and edema. Our research has shown that when the Neuro-Spinal Scaffold is placed at the epicenter of the contusion injury, it modulates the healing process by providing a biocompatible and cellular-adhesive support that promotes appositional healing.

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 SCI patients. In the future, we may attempt to further enhance the performance of our Neuro-Spinal Scaffold by multiple combination strategies involving electrostimulation devices, additional biomaterials, drugs approved by the U.S. Food & Drug Administration ("FDA"), or growth factors.

Regulatory Pathway of Neuro-Spinal Scaffold

Our Neuro-Spinal 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 (PMA) Application before we can begin selling the product in the United States. A PMA application must be supported by extensive data including, but not limited to, technical information regarding device design and development, pre-clinical and clinical trials, data and manufacturing and labeling to support the FDA's determination that there is reasonable assurance that the device is safe and effective for its intended use.

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. An HDE application is similar in form and content to a PMA application and,although exempt from the effectiveness requirements of a PMA, an HDE does require sufficient 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.

Upon receipt of a PMA or HDE application, the FDA makes a threshold determination as to whether the application is sufficiently complete to permit a substantive review. If the FDA makes this determination, it will accept the application for filing. Once the submission is accepted for filing, the

FDA begins an in-depth review of the application. An FDA review of a PMA application generally takes one to three years from the date the application is accepted for filing, though it may take significantly longer; review of an HDE application can be shorter than a PMA. The review period is often significantly extended by requests for more information or clarification of information already provided in the submission. During the review period, the submission may be sent to an FDA-selected scientific advisory panel composed of physicians and scientists with expertise in the particular field. The FDA scientific advisory panel issues a recommendation to the FDA that may include conditions for approval. The FDA is not bound by the recommendations of the advisory panel. Toward the end of the PMA or HDE application review process, the FDA will conduct an inspection of the manufacturer's facilities to ensure that the facilities are in compliance with Quality System Regulations, or QSRs. If the FDA evaluations of both the PMA/HDE application and the manufacturing facilities are favorable, the FDA will issue a letter approving the application. This letter often contains a number of conditions, which must be met in order to commercialize the device for specified indications and intended uses.

Regulatory approvals, if granted, may include significant labeling limitations and limitations on the indicated uses for which the product may be marketed. Conditions of approval for a PMA/HDE application also often include the requirement to conduct a post-market study or studies. In addition, to obtain regulatory approvals and clearances, the FDA imposes numerous other requirements with which medical device manufacturers must comply. Any products we manufacture or distribute under FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA.

We are required to conduct human clinical trials to obtain evidence of safety and the probable benefit to health before an HDE can be submitted to the FDA. Before clinical studies can commence, an Investigational Device Exemption application (IDE) must be submitted to and approved by the FDA. The completion of the human clinical studies and obtaining the FDA approval of an HDE 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 HDE. In 2013, the FDA approved our IDE application for the pilot study and granted HUD designation for our Neuro-Spinal Scaffold.

In the future, if our Neuro-Spinal Scaffold is approved via either the PMA or HDE pathway, modifications or enhancements that could significantly affect the safety or effectiveness of the device or that constitute a major change to the intended use of the device will require new PMA or HDE application and approval. Other changes may require a supplement or other change notification that must be reviewed and approved by the FDA. Modified devices for which a new PMA or HDE application, supplement or notification is required cannot be distributed until the application is approved by the FDA. An adverse determination or a request for additional information could delay the market introduction of new products, which could have a material adverse effect on our business, financial condition and results of operations. We may not be able to obtain PMA or HDE approval in a timely manner, if at all, for the Neuro-Spinal Scaffold or any future devices or modifications to Neuro-Spinal Scaffold or such devices for which we may submit a PMA or HDE application.

Pre-Clinical and Non-Clinical Studies

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 with non-clinical models using different species and different methods of inducing SCI. In our pre-clinical studies, we utilized rat, non-human primate, and pig models because each exhibits 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 rat and pig models of spinal contusion injury.

The first non-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. Subsequently, the safety and efficacy of implantation of the bioresorbable polymer scaffold device was evaluated in rats with spinal cord contusion injury. 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, larger rat contusion studies were performed in 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 model, the BBB score was not improved by the scaffold device. However, implantation of the bioresorbable polymer scaffold device into the necrotic zone of the injured spinal cord resulted in appositional healing and tissue remodeling that preserved spinal cord architecture. Morphometric analysis of spinal sections stained with hematoxylin & eosin revealed that non-implanted rats with contusion injury developed large cavities surrounded by a thin rim of spared white matter. In contrast, rats treated with the implanted bioresorbable polymer scaffold device demonstrated decreased cavity volume along with increased amounts of spared and remodeled tissue at the lesion epicenter. Cavitation following spinal contusion injury, particularly if progressive, can impair recovery and result in serious clinical symptoms. These results indicate that implantation of the bioresorbable polymer scaffold device in the acutely injured rat spinal cord can provide the benefit of preserving spinal cord architecture through reduced cavitation, and promotion of white matter sparing and tissue remodeling.

The spinal cord anatomy of non-human primates is very similar to that of humans. We performed a series of studies in African green monkeys 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 to non-implant controls, and improved recovery of locomotion in subjects with full unilateral hemisection lesions.

The pig has been used as a large animal model of spinal cord contusion injury due to similarities in size and structure to the human spinal cord. We evaluated the surgical feasibility of implanting the bioresorbable polymer scaffold device in a spinal cord after a contusion injury in the pig model. Severe

contusion injuries were created in Gottingen pigs with a weight drop apparatus. At approximately 4, 6, and 24 hours after contusion injury, pigs underwent the bioresorbable polymer scaffold device surgical implantation procedure. At each time point, a large volume of necro-hemorrhagic fluid and debris rapidly effluxed from the injury site, releasing built-up pressure and resulting in a substantial cavity in the center of the spinal cord. Bioresorbable polymer scaffold devices were easily placed into the resulting contusion-induced spinal cord cavity. Increased spinal tissue pressure after contusion injury results in reduced blood perfusion and ischemia in damaged spinal tissue, and is an important contributor to the pathophysiology of spinal cord injury. We measured intraspinal pressure (using catheter pressure probes) at the contusion epicenter in the pigs before, during, and after the surgical procedure. As expected, contusion injury elevated intraspinal tissue pressure compared to normal values. Surgical implantation of the bioresorbable polymer scaffold device resulted in a return of intraspinal tissue pressure to physiologically normal levels.

Taken together, the results from these non-clinical studies in two rat spinal cord injury models, in the African green monkey unilateral hemisection injury model, and the pig contusion injury model, demonstrate that the bioresorbable polymer scaffold device, surgically implanted at the epicenter of the wound after an acute spinal cord injury, acts by appositional healing to spare spinal cord tissue, decrease post-traumatic cyst formation, and decrease spinal cord tissue pressure in preclinical models of spinal cord contusion injury.

Pilot Study

Our Neuro-Spinal Scaffold is currently being studied in an early feasibility, five subject pilot study under our approved IDE application for the treatment of complete traumatic acute spinal cord injury. The FDA approved the study which is intended to capture safety and feasibility of the Neuro-Spinal Scaffold for the treatment of complete functional spinal cord injury, as well as to gather preliminary evidence of the clinical effectiveness of the Neuro-Spinal Scaffold.

The pilot study was initially approved for up to three clinical sites across the United States, and as of October 2014, the number of allowable clinical sites was increased to up to 20. The FDA also approved various changes to the protocol for the study related to the broadening of the study's eligibility criteria. In October 2014, we also announced that the first subject was enrolled in our pilot study at the Barrow Neurological Institute in Phoenix, Arizona. Under the conditions of the FDA's approval of our IDE application, our pilot study was initially staggered such that each patient that meets the eligibility criteria would be followed for three months prior to enrolling the next patient in the study. In December 2014, barring significant safety issues, the FDA approved an expedited enrollment plan. In January 2015, about three months after the first subject was enrolled, we opened enrollment and our second subject was enrolled subsequently thereafter. We intend to submit one month of safety data for that subject to the FDA together with the previous subject's data, and we will then be able to have concurrent enrollment for the remaining three subjects. There will be no additional mandatory holds between enrollment of the final three subjects.

We anticipate full enrollment of five patients in the pilot study in 2015. If our pilot study is successful, we then expect to conduct a pivotal study to show safety and probable benefit in order to obtain FDA approval to commence commercialization under a HDE. We currently expect the pivotal study will begin in 2016, with estimated completion in 2017. However, even if we are able to obtain FDA approval of our Neuro-Spinal Scaffold, because the Neuro-Spinal Scaffold is 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 and there can be no assurance that we will be able to do so. For major markets outside the United States, we would be required to seek regulatory approvals in those markets after the clinical studies or trials are conducted in the United States.

Neuro-Spinal Scaffold Plus Neural Stem Cells (Bioengineered Neural Tissue)

We are also developing a version of our Neuro-Spinal Scaffold that is combined with neural stem cells for the treatment of chronic SCI. It is well known that for neural stem cells to appropriately differentiate and project neural processes, a solid support is required. The Neuro-Spinal Scaffold was designed as a carrier for neural stem cells that promotes attachment, sprouting, and survival. As opposed to other neural stem cell therapies that involve the injection of suspensions of neural stem cells around the glial scar, our approach is to pre-differentiate neural stem cells on a scaffold, creating a "bioengineered neural tissue," and then to have neurosurgeons surgically remove the glial scar to create a well-defined bed into which the Bioengineered Neural Tissue can be implanted. We believe that this Bioengineered Neural Tissue will promote the generation of new neural circuitry, bridging the gap between neural networks above and below the level of injury. Currently, we have evaluated Bioengineered Neural Tissue in two non-clinical experiments and further study is ongoing.

Regulatory Pathway of Neuro-Spinal Scaffold Plus Neural Stem Cells

Our Neuro-Spinal Scaffold Plus Neural Stem Cells is expected to be regulated as a combination product. Combination products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products. Because combination products involve components that would normally be regulated under different types of regulatory authorities, and frequently by different centers of the FDA, they raise challenging regulatory, policy, and review management challenges. Differences in regulatory pathways for each component of the product can impact the regulatory processes for all aspects of product development and management, including preclinical testing, clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, and post-approval modifications.

A combination product is assigned to an FDA Agency Center or alternative organizational component that will have primary jurisdiction for its premarket review and regulation. Under section 503(g)(1) of the FDCA, assignment to a center with primary jurisdiction, or a lead center, is based on a determination of the "primary mode of action," or PMOA, of the combination product. Stem cell-based therapies are regulated under the jurisdiction of Center for Biologics Evaluation and Research (CBER) typically requiring an Investigational New Drug (IND) application and a Biologics License Application (BLA) for marketing approval. The formal jurisdiction assignment process is achieved through the request for designation (RFD) process. We expect to submit a RFD to the Office of Combination Products (OCP) for their jurisdictional determination for the lead center and applicable regulatory pathway for our Neuro-Spinal Scaffold Plus Neural Stem Cells.

Bioresorbable Hydrogels

We are also evaluating a family of resorbable hydrogels for localized cell therapies for spinal cord injury.

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.

We hold an exclusive worldwide license to a broad suite of patents co-owned by BCH and MIT covering the use of a wide range of polymers to treat SCI, and to promote the survival and proliferation of human stem cells in the spinal cord (the "BCH License"). Issued patents and pending patent applications licensed under the BCH License cover the technology underlying our Neuro-Spinal

Scaffold and the use of a wide range of biomaterial scaffolding for treating SCI by itself or in combination with drugs, growth factors or human stem cells. The BCH License covers 7 issued United States patents and 20 issued international patents expiring between 2015 and 2026, and two pending United States patents and 12 pending international patents.

The BCH 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 BCH. In connection with our acquisition of the BCH License, we submitted to a 5-year development plan to BCH and MIT that includes certain targets and projections related to the timing of product development and regulatory approvals. We are required to either meet the stated targets and projections in the plan, or notify BCH and revise the plan. BCH has the right to terminate the BCH License for failure by us to either meet the targets and projections in the plan or our failure submit an acceptable revision to the plan within a 60-day cure period after notification by BCH that we are not in compliance with the plan. We are currently in compliance with our plan.

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

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

Research and Development Expenditures

Our research and development expenditures, which include research and development related to our product candidates, were $10,273,000, $10,533,000 and $6,376,000 in 2014, 2013 and 2012, respectively.

Competition

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, design and implementation of clinical trials, regulatory processes and obtaining regulatory approval for products, 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 if they have collaborative arrangements with larger and more established biotechnology 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 compete effectively, we will have to make substantial investments in development, clinical 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 any of 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 Neuro-Spinal Scaffold. We manufacture our scaffolds following FDA regulations for design controls using two fully operational manufacturing cleanrooms located at our facility in Cambridge, Massachusetts. 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. Currently, we are working with two preferred vendors for our critical raw materials; however, these materials are also available from other vendors. We are currently manufacturing our Neuro-Spinal Scaffold to support our pilot clinical study.

Sales and Marketing

If we obtain approval from the FDA, or another foreign regulatory body, to commercialize our products, we plan to establish a direct sales force to sell our products to major markets in the United States and to sell through distributors in foreign markets. We anticipate the direct sales force, once and if established, 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 implement medical education programs intended for outreach to practitioners in physical medicine and rehabilitation centers and 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 discussed 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

As of December 31, 2014, we had 31 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.

Corporate Information

We incorporated under the laws of the state of Nevada on April 2, 2003 as 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. We changed our name to InVivo Therapeutics Holdings Corp. in connection with the transaction.

Our offices are located at One Kendall Square, Suite B14402, Cambridge, Massachusetts 02139, and our telephone number is 617-863-5500. Our website is www.invivotherapeutics.com. Information contained on, or accessible through, our website is not a part of, and is not incorporated by reference into, this Annual Report.

Available Information

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 reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports. Information appearing on our website is not a part of, and is not incorporated in, this Annual Report.

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 at www.sec.gov that contains reports, proxy and information statements and other information that we file electronically with the SEC.

Item 1A. RISK FACTORS

Certain factors may have a material adverse effect on our business, financial condition, and results of operations. You should consider carefully the risks and uncertainties described below, in addition to other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and related notes. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. If any of the following risks actually occurs, our business, financial condition, results of operations, and future prospects could be materially and adversely affected.

Risks Related to Our Business

We have a limited operating history and have incurred significant losses since our inception.

We have incurred net losses each year since our inception, including net losses of $18.3 million for the year ended December 31, 2014, and $38.7 million for the year ended December 31, 2013. As of December 31, 2014, we had an accumulated deficit of $100.3 million. To date, we have not commercialized any products or generated any revenues from the sale of products, and we do not expect to generate any product revenues in the foreseeable future. We do not know whether or when we will generate revenue or become profitable.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities related to our Neuro-Spinal Scaffold. Overall, we expect our research and development 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. Our lead product candidate, Neuro-Spinal Scaffold, is currently being studied in a pilot study and, as a result, we expect that it will be several years, if ever, before we have a product candidate ready for commercialization. Even if we obtain regulatory approval to market our Neuro-Spinal Scaffold or other products, our future revenues will depend upon the size of any markets in which our products have received approval, our ability to achieve sufficient market acceptance, reimbursement from third-party payors and other factors.

We anticipate that we will continue to incur substantial losses for the foreseeable future and may never achieve or maintain profitability.

We expect to continue to incur significant expenses and increasing net losses for at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- continue our pilot study and if successful, prepare for a pivotal study of Neuro-Spinal Scaffold;
- continue the research and development of our other product candidates;
- have our product candidates manufactured for clinical trials and for commercial sale;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, protect and expand our intellectual property portfolio; and
- continue our research and development efforts for new product opportunities.

To become and remain profitable, we must succeed in developing and commercializing our product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, developing additional product candidates, obtaining regulatory approval for these product

candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the initial stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could depress the value of our Company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our Company could cause you to lose all or part of your investment.

We will need additional funding in the future. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our clinical studies of, and seek regulatory approval for, our Neuro-Spinal Scaffold. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to manufacturing, marketing, sales and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

As of December 31, 2014, our consolidated cash balance was approximately $13.5 million. In addition, as a result of a January 2015 financing that provided us with $11 million in net proceeds, we believe our current cash and cash equivalents are adequate to fund our operations into the fourth quarter of 2016. Our future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of preclinical development, laboratory testing and clinical studies for our Neuro-Spinal Scaffold and any other product candidates that we may develop or acquire;
- future clinical trial results of our Neuro-Spinal Scaffold;
- the timing of, and the costs involved in, obtaining regulatory approvals for the Neuro-Spinal Scaffold if our pilot and pivotal studies are successful, and the outcome of regulatory review of the Neuro-Spinal Scaffold;
- the cost and timing of future commercialization activities for our products, if any of our product candidates are approved for marketing, including product manufacturing, marketing, sales and distribution costs;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the cost of having our product candidates manufactured for clinical trials in preparation for regulatory approval and in preparation for commercialization;
- the cost and delays in product development as a result of any changes in regulatory oversight applicable to our product candidates;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- the cost and timing of establishing sales, marketing and distribution capabilities;

- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio;
- the efforts and activities of competitors and potential competitors;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings and other third-party funding alternatives including license and collaboration agreements. To raise additional capital or pursue strategic transactions, we may in the future sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock which will dilute the ownership interest of our current stockholders, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our current stockholders. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us or that may reduce the value of our common stock. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for our Neuro-Spinal Scaffold or any other product candidates that we develop or acquire.

We license certain technology underlying the development of our Neuro-Spinal Scaffold from BCH and MIT, and the loss of the license would result in a material adverse effect on our business, financial position and operating results and cause the market value of our common stock to decline.

We license technology from BCH and MIT that is integrated into our Neuro-Spinal Scaffold under an exclusive license. Under the license agreement, we have agreed to milestone payments and to meet certain reporting obligations. In the event that we were to breach any of the obligations under the agreement and fail to timely cure, BCH and MIT would have the right to terminate the agreement upon notice. In addition, BCH and MIT have the right to terminate our license upon the bankruptcy or receivership of the Company. If we are unable to continue to use or license this technology on reasonable terms, or if this technology fails to operate properly, we may not be able to secure alternatives in a timely manner and our ability to develop our products could be harmed.

We depend heavily on the success of one product candidate, Neuro-Spinal Scaffold, which is currently being studied in a pilot study. Even if we obtain favorable clinical results, we may not be able to obtain regulatory approval for, or successfully commercialize, our Neuro-Spinal Scaffold.

We currently have only one product candidate, Neuro-Spinal Scaffold, in clinical development, and our business depends almost entirely on the successful clinical development, regulatory approval and commercialization of that product candidate, which may never occur. We currently have no products available for sale, generate no revenues from sales of any products, and we may never be able to develop marketable products. Our Neuro-Spinal Scaffold, which is currently being studied in an ongoing pilot study, will require substantial additional clinical development, testing, manufacturing process development, and regulatory approval before we are permitted to commence its commercialization. Our other product candidate, Bioengineered Neural Tissue, is in preclinical development. The clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidates. Before obtaining regulatory approval via the HDE pathway for the commercial sale of any product candidate, we must demonstrate through extensive preclinical testing and clinical trials, at least that the product candidate 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, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Alternatively, if we were to seek PMA approval for our product candidates, that would require demonstration that the product is safe and effective for use in each target indication. This process can take many years. Of the large number of medical devices in development in the United States, only a small percentage successfully complete the FDA regulatory approval process and are commercialized. Accordingly, even if we are able to obtain the requisite capital to continue to fund our development and clinical programs, we may be unable to successfully develop or commercialize our Neuro-Spinal Scaffold.

We may experience delays in our ongoing pilot study for our Neuro-Spinal Scaffold, and we do not know whether future clinical trials of our Neuro-Spinal Scaffold, or other future product candidates, will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all.

Before we can obtain regulatory approval for the sale of our Neuro-Spinal Scaffold, we must complete pilot and pivotal clinical studies. Our Neuro-Spinal Scaffold is currently being studied in an early feasibility, five subject pilot study under our approved IDE application for the treatment of complete traumatic acute spinal cord injury. 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 initial results of our clinical studies in humans are promising, our results 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 enrollment of subjects in the study, the availability of scaffolds to supply to our clinical sites, failure to demonstrate safety and efficacy of our Neuro-Spinal Scaffold, lack of adequate funding to continue the clinical trial, or unforeseen safety issues.

In additional, clinical trials can be delayed or aborted for a variety of reasons, including delay or failure to:

- obtain regulatory approval to commence a clinical trial;
- reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtain institutional review board, or IRB, approval at each site;

- recruit, enroll and retain patients through the completion of clinical trials;
- maintain clinical sites in compliance with trial protocols through the completion of clinical trials;
- address any patient safety concerns that arise during the course of the trial;
- initiate or add a sufficient number of clinical trial sites; or
- manufacture sufficient quantities of our product candidate for use in clinical trials.

We could encounter delays if a clinical trial is suspended or terminated by us, by the relevant IRBs at the sites at which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, or changes in laws or regulations. Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly.

We may find it difficult to enroll patients in our clinical studies, which could delay or prevent clinical studies of our product candidates.

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical studies depends on the speed at which we can recruit patients to participate in testing our product candidates. If we have difficulty enrolling a sufficient number of patients to conduct our clinical studies as planned, we may need to delay, limit or terminate ongoing or planned clinical studies, any of which would have an adverse effect on our business.

Patient enrollment is affected by a number of factors including:

- severity of the disease or condition under investigation;
- design of the study protocol;
- size and nature of the patient population;
- eligibility criteria for and design of the study in question;
- perceived risks and benefits of the product candidate under study;
- proximity and availability of clinical study sites for prospective patients;
- availability of competing therapies and clinical studies;
- efforts to facilitate timely enrollment in clinical studies;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

We may not be able to initiate or continue clinical studies if we cannot enroll a sufficient number of eligible patients to participate in the clinical studies required by regulatory agencies. If we have difficulty enrolling a sufficient number of patients to conduct our clinical studies as planned, we may need to delay, limit or terminate ongoing or planned clinical

studies, any of which would have an adverse effect on our business.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

The results of preclinical studies and early clinical trials of new medical devices do not necessarily predict the results of later-stage clinical trials. The design of our clinical trials is based on many assumptions about the expected effects of our product candidates, and if those assumptions are incorrect, the trials may not sufficiently produce results to support regulatory applications. We are currently pursuing marketing approval via HDE which requires us to show the device doesn't pose an unreasonable or significant risk of illness or injury, and that the probable benefit of health outweighs the risk of injury or illness from its use. Preliminary results may not be confirmed upon full analysis of the detailed results of an early clinical trial. Product candidates in later stages of clinical trials may fail to show safety and probable benefit sufficient to support intended use claims despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidates may not be sufficient to obtain regulatory approval in the United States or elsewhere. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile. Because of the uncertainties associated with clinical development and regulatory approval, we cannot determine if or when we will have an approved product for commercialization or achieve sales or profits.

We must obtain 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 Neuro-Spinal Scaffold 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 the Neuro-Spinal Scaffold 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, or may also require additional testing. 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 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.

There are risks associated with pursuing FDA approval via an HDE pathway, including the possibility that the approval could be withdrawn in the future, as well as limitations on the ability to profit from sales of the product.

Our Neuro-Spinal Scaffold is expected to be regulated by the FDA as a Class III medical device, requiring either PMA or HDE approval. A HUD designation was granted for the Neuro-Spinal Scaffold in 2013, opening the HDE pathway. The FDA's approval of an HDE to treat that qualifying patient population then requires demonstration that the device is safe for its intended application, that

it is potentially effective, and that the probable benefits outweigh the associated risks. If a competitor device subsequently becomes available through the PMA process that addresses the same patient population as the HDE device, the HDE device may need to be withdrawn from the U.S. market.

In addition, except in certain circumstances, products approved under an HDE cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (i.e., for profit). Currently, a product is only eligible to be sold for profit after receiving HDE approval if the device (1) is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or (2) is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe. If an HDE-approved device does not meet either of the eligibility criteria, the device cannot be sold for profit.

Our medical device products and operations are subject to extensive governmental regulation both in the United States and abroad, and our failure to comply with applicable requirements could cause our business to suffer.

Our medical device products and operations are subject to extensive regulation by the FDA and various other federal, state and foreign governmental authorities. Government regulation of medical devices is meant to assure their safety and effectiveness, and includes regulation of, among other things:d

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales and distribution;
- regulatory clearances and approvals including premarket clearance and approval;
- conformity assessment procedures;
- product traceability and record keeping procedures;
- advertising and promotion;
- product complaints, complaint reporting, recalls and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market studies; and
- product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

Before we can market or sell a new regulated product in the United States, we must obtain clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act (FDCA), approval of a PMA application, or approval of a HDE, unless the device is specifically exempt from premarket review. Our Neuro-Spinal Scaffold is expected to be regulated by the FDA as a Class III

medical

device, requiring either PMA or HDE approval. A HUD designation was granted for the Neuro-Spinal Scaffold in 2013, opening the HDE pathway.

In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. Modifications to products that are approved through a PMA application generally need FDA approval. The process of obtaining a PMA is costly and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA until an approval is obtained.

An HDE application is similar in form and content to a PMA application and, although exempt from the effectiveness requirements of a PMA, an HDE does require sufficient 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.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that our products are safe and effective for their intended uses;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions that may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. For example, in 2011, the FDA announced a Plan of Action to modernize and improve the FDA's premarket review of medical devices, and has implemented, and continues to implement, reforms intended to streamline the premarket review process. In addition, as part of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, Congress enacted several reforms entitled the Medical Device Regulatory Improvements and additional miscellaneous provisions which will further affect medical device regulation both pre- and post-approval. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products.

In addition, even after we have obtained the proper regulatory clearance or approval to market a product, the FDA has the power to require us to conduct postmarketing studies. Failure to conduct required studies in a timely manner could result in the revocation of approval for the product that is subject to such a requirement and could also result in the recall or withdrawal of the product, which would prevent us from generating sales from that product in the United States.

Failure to comply with applicable laws and regulations could jeopardize our ability to sell our products and result in enforcement actions such as:

- warning letters;
- fines;
- injunctions;
- civil penalties;
- termination of distribution;
- recalls or seizures of products;

- delays in the introduction of products into the market;
- total or partial suspension of production;
- refusal of the FDA or other regulator to grant future clearances or approvals;
- withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and/or
- in the most serious cases, criminal penalties.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, results of operations and financial condition.

If we or our suppliers fail to comply with ongoing FDA regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA. In particular, we and our third-party suppliers will be required to comply with the FDA's QSRs. These FDA regulations cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of products. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. If we, or our manufacturers, fail to adhere to QSR requirements, this could delay production of our product candidates and lead to fines, difficulties in obtaining regulatory clearances, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

In addition, the FDA audits compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Any of these sanctions could have a material adverse effect on our reputation, business, results of operations and financial condition. Furthermore, our key component suppliers may not currently be or

may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

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

In general, the biotechnology industry 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, design and implementation of clinical trials, regulatory processes and approval for products, production and manufacturing, and sales and marketing of approved products.

Large and established companies compete in the biotechnology 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 if they have collaborative arrangements with larger and more established biotechnology 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, clinical 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 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 of our product candidates for reasons both within and outside of our control.

We have limited experience manufacturing our Neuro-Spinal Scaffold for clinical-study scale and no experience for commercial scale.

To date, we have manufactured our Neuro-Spinal Scaffold on a small scale, including sufficient supply that is needed for our clinical studies. We may encounter unanticipated problems in the scale-up process that will result in delays in the manufacturing of the Neuro-Spinal Scaffold, and therefore, delay our clinical studies. During our clinical trials, we are subject to FDA regulations requiring manufacturing of our scaffolds with 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 rely on third-party suppliers and vendors for certain 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 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 CROs to conduct certain of our laboratory testing, animal and human clinical studies. These third parties may not complete testing activities on schedule. 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 these third parties does not relieve us of these responsibilities and requirements. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our product candidates.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Future growth will impose significant added responsibilities on members of our management. Our future financial performance and our ability to commercialize our Neuro-Spinal Scaffold, if approved, and any other product candidates, and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and, if necessary, sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our Company.

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 our products will depend on, among other things, their acceptance by physicians, patients, third-party payors such as health insurance companies and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. Physicians and hospitals will need to establish training and procedures to utilize and implement our Neuro-Spinal Scaffold, and there can be no assurance that these parties will adopt the use of our device or develop sufficient training and procedures to properly utilize it. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, both within and outside of our control. If our product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business.

If we obtain approval for our products, their commercial success will depend in part upon the level of reimbursement we receive from third parties 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 our products and related treatments will be available from third-party payors such as 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.

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.

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 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.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from collaborators, prospective licensees and other third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

We are subject to a pending securities class action and related shareholder demands, which could divert management's attention and harm our business.

We are the subject of a securities class action lawsuit. The lawsuit, filed in July 2014, alleges violations of the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements related to the timing and completion of the clinical study of our Neuro-Spinal Scaffold. In January 2015, we received a purported shareholder demand alleging breach of fiduciary duties allegedly related to the claimed false and misleading statements that are the subject of the securities class action. We believe that this action is without merit and intend to defend it vigorously. No assurance can be provided that we will be successful in defending this claim or that insurance proceeds will be sufficient to cover any liability under such claims. Further, the amount of time that will be required to resolve these lawsuits is unpredictable and these actions may divert management's attention from the day-to-day operations of our business, which could adversely affect our business, results of operations and cash flows.

We face potential product liability claims, 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 for the healthcare industry is expensive and sometimes difficult to obtain. We may not be able to maintain such insurance on acceptable terms or be able to secure increased coverage if the commercialization of our products progresses, nor can we be sure that existing or future claims against us will be covered by our product liability insurance. Moreover, the existing coverage of our insurance policy or any rights of indemnification and contribution that we may have may not be sufficient to offset existing or future 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 our management's attention.

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 environmental, health and safety laws and regulations, including those 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. 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 and development efforts.

Risks Related to Investment in Our Securities

"Penny stock" rules may make buying or selling our securities difficult which may make our stock less liquid and make it harder for investors to buy and sell our securities.

Trading in our securities is subject to the SEC's "penny stock" rules and it is anticipated that trading in our securities will continue to be subject to the penny stock rules for the foreseeable future. The SEC has adopted rules which generally establish the definition of a "penny stock" to be 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. These rules require that any broker-dealer who recommends our securities to persons other than prior customers and accredited investors must, prior to the sale, make a special written suitability determination for the purchaser and receive the purchaser's written agreement to execute the transaction. Unless an exception is available, the regulations require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the risks associated with trading in the penny stock market. In addition, broker-dealers must disclose commissions payable to both the broker-dealer and the registered representative and current quotations for the securities they offer. The additional burdens imposed upon broker-dealers by these requirements may discourage broker-dealers from recommending transactions in our securities, which could severely limit the liquidity of our securities and consequently adversely affect the market price for our securities.

Our common stock is quoted on the OTCQB, 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 OTCQB tier of OTC Markets Group, Inc., an inter-dealer automated quotation system for equity securities not listed on a national securities exchange. Quotation of our common stock on the OTCQB 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 OTCQB 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.

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:

- the status, completion and/or results of our clinical trials;
- actual or anticipated variations in our operating results;
- announcements of developments by us or our competitors;
- 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;
- 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, 2014, there were outstanding warrants to purchase 10,208,849 shares of our common stock, and outstanding options to purchase 10,445,662 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 quoted on the OTCQB.

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 our 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 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 believe that 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.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

We lease approximately 26,150 square feet of office, laboratory and manufacturing space in Cambridge, Massachusetts. The lease commenced in November 2011, and is for an initial term of six years and three months, with one five-year extension. We believe the facility is adequate to meet our current needs and that additional space will be available on commercially reasonable terms as needed.

Item 3. LEGAL PROCEEDINGS

Lawsuit with Former Employee

In November 2013, we filed a lawsuit against Francis Reynolds, our 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 monetary damages and an accounting. The lawsuit involves approximately $500,000 worth of personal and/or exorbitant expenses that we allege Mr. Reynolds inappropriately caused us to pay while he was serving as our Chief Executive Officer, Chief Financial Officer, President and Chairman of our Board of Directors. On December 6, 2013, Mr. Reynolds answered the complaint, and filed counterclaims against us and our 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 we 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, we, along with the directors named in the counterclaims, filed our answer. The parties are currently conducting pre-trial discovery. No judgments or rulings are pending at this stage.

Shareholder Matters and Investigations

On July 31, 2014, a putative securities class action lawsuit was filed in the United States District Court for the District of Massachusetts, naming the Company and Mr. Reynolds, as defendants (the "Securities Class Action"). The lawsuit alleges violations of the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements related to the timing and completion of the clinical study of our Neuro-Spinal Scaffold. The plaintiff seeks class certification for purchasers of our common stock during the period from April 5, 2013 through August 26, 2013 and unspecified damages. On December 12, 2014, we moved to dismiss this lawsuit, and a hearing on that motion is scheduled for March 24, 2015. We intend to vigorously defend the lawsuit.

On January 23, 2015, Shawn Luger, a purported shareholder of the Company, sent us a letter demanding that the Board of Directors take action to remedy purported breaches of fiduciary duties allegedly related to the claimed false and misleading statements that are the subject of the Securities Class Action (the "Shareholder Demand"). The Board of Directors is currently considering this demand.

In addition to the Securities Class Action and the Shareholder Demand, we have received investigation subpoenas from the Boston Regional Office of the Securities and Exchange Commission and the Massachusetts Securities Division of the Secretary of the Commonwealth of Massachusetts requesting corporate documents also concerning, among other topics, the allegations raised Securities Class Action and the Shareholder Demand. We are currently cooperating with these investigations.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

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 OTCQB under the symbol "NVIV." The following table shows the high and low bid prices for our Common Stock based upon quotations on the OTCQB for each quarter in the periods presented:

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

Fiscal Quarter Ended	High Bid	Low Bid
December 31, 2014	$ 1.60	$ 0.49
September 30, 2014	$ 1.21	$ 0.47
June 30, 2014	$ 2.25	$ 0.93
March 31, 2014	$ 2.67	$ 1.49

These over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, markdown or commissions and may not necessarily represent actual transactions. The high and low bid prices listed have been rounded up to the next two decimal places.

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.

Holders

As of March 5, 2015, we had approximately 377 stockholders of record. This figure does not reflect persons or entities that hold their stock in nominee or "street" name through various brokerage firms.

Equity Compensation Plans

The information required to be disclosed by Item 201(d) of Regulation S-K, "Securities Authorized for Issuance Under Equity Compensation Plans," is incorporated herein by reference. Refer to Item 12 of Part III of this Annual Report on Form 10-K for additional information.

Recent Sales of Unregistered Securities

None.

Issuer Repurchases of Equity Securities

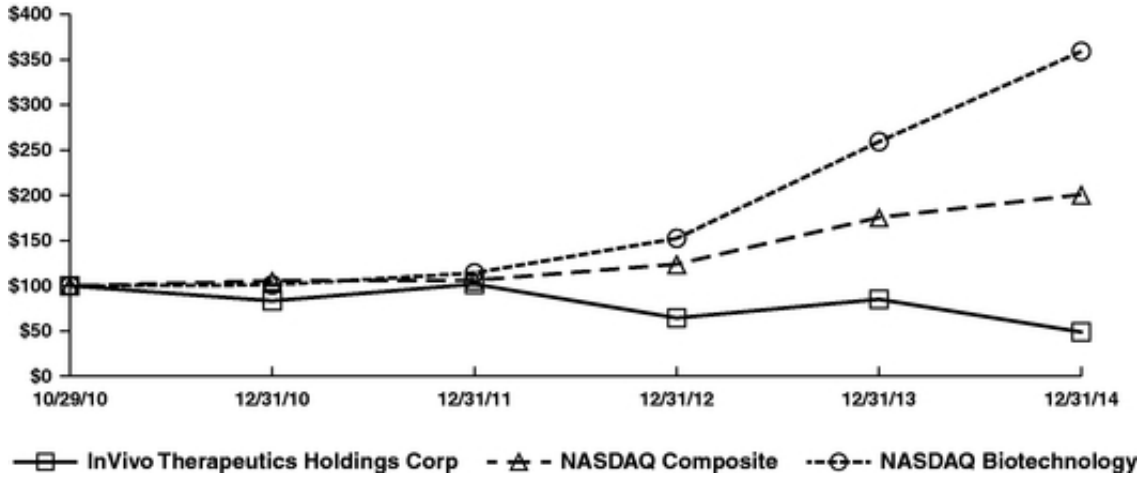
None.

Performance Graph

The following performance graph and related information shall not be deemed to be "soliciting material" or to be "filed" with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act, each as amended, except to the extent that we specifically incorporate it by reference into such filing.

The following graph compares our cumulative 50-Month cumulative total shareholder return on common stock with the cumulative total returns of the NASDAQ Composite Index and the NASDAQ Biotechnology Index from October 29, 2010 to December 31, 2014. The comparison assumes $100 was invested on October 29, 2010 and in each of the foregoing indices and assumes reinvestment of dividends, if any. The points on the graph are as of December 31st of the year indicated.

COMPARISON OF 50 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.

		December 31,				
	10/29/10	2010	2011	2012	2013	2014
InVivo Therapeutics Holdings Corp	$ 100.00	$ 83.33	$ 101.85	$ 64.44	$ 85.04	$ 48.89
NASDAQ Composite Index	$ 100.00	$ 105.54	$ 106.11	$ 123.88	$ 175.53	$ 200.78
NASDAQ Biotechnology Index	$ 100.00	$ 100.90	$ 114.21	$ 152.38	$ 259.25	$ 358.99

Item 6. SELECTED FINANCIAL DATA

The selected financial data presented below is derived from our audited consolidated financial statements. You should read the selected historical combined financial data set forth below in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 of Part II to this Annual Report. Unless otherwise indicated, all amounts in this Item 6 are presented in thousands, except share and per-share data.

InVivo Therapeutics Holdings Corp.
Consolidated Balance Sheets

	December 31,				
	2014	2013	2012	2011	2010
ASSETS :					
Current assets:					
Cash and cash equivalents	$ 13,459	$ 13,980	$ 12,825	$ 4,364	$ 8,964
Restricted cash	422	602	601	548	—
Prepaid expenses and other current assets	1,072	20	144	104	81
Total current assets	14,953	14,602	13,570	5,016	9,045
Property and equipment, net	1,605	2,337	2,312	520	280
Other assets	135	157	180	166	54
Total assets	$ 16,693	$ 17,096	$ 16,062	$ 5,702	$ 9,379
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT):					
Current liabilities:					
Accounts payable	$ 569	$ 899	$ 1,152	$ 567	$ 337
Loan payable-current portion	320	—	—	51	—
Note payable-current portion	18	74	—	—	—
Capital lease payable-current portion	—	3	33	31	—
Derivative warrant liability	7,224	—	14,585	35,473	10,647
Accrued expenses	1,044	1,292	1,021	618	248
Total current liabilities	9,175	2,268	16,791	36,740	11,232
Loan payable-less current portion	1,600	1,920	1,578	84	—
Note payable-less current portion	—	18	—	—	—
Capital lease payable-less current portion	—	—	3	38	—
Total liabilities	10,775	4,206	18,372	36,862	11,232
Commitments and contingencies					
Stockholders' equity (deficit):					
Common stock, $0.00001 par value(1)	1	1	1	1	1
Additional paid-in capital	106,172	94,798	40,842	16,656	11,235
Accumulated deficit	(100,255)	(81,909)	(43,153)	(47,817)	(13,089)
Total stockholders' equity (deficit)	5,918	12,890	(2,310)	(31,160)	(1,853)
Total liabilities and stockholders' equity (deficit)	$ 16,693	$ 17,096	$ 16,062	$ 5,702	$ 9,379

(1) Authorized—200,000,000 shares; issued and outstanding—93,812,000, 78,773,736, and 65,881,122 at

December 31, 2014, 2013 and 2012, respectively. Authorized—100,000,000 shares; issued and outstanding—53,760,471 and 51,647,171 shares at December 31, 2011 and 2010, respectively.

InVivo Therapeutics Holdings Corp.
Consolidated Statement of Operations

	Years Ended December 31,				
	2014	2013	2012	2011	2010
Operating expenses:					
Research and development	$ 10,273	$ 10,533	$ 6,376	$ 4,103	$ 1,673
General and administrative	7,566	8,472	6,403	4,556	1,724
Total operating expenses	17,839	19,005	12,779	8,659	3,397
Operating loss	(17,839)	(19,005)	(12,779)	(8,659)	(3,397)
Other income (expense):					
Interest income	5	15	35	9	3
Interest expense	(136)	(130)	(72)	(13)	(564)
Modification of warrants	—	(765)	—	—	—
Derivatives gain (loss)	(376)	(18,871)	17,480	(26,065)	(3,953)
Other income (expense), net	(507)	(19,751)	17,443	(26,069)	(4,514)
Net income (loss)	$ (18,346)	$ (38,756)	$ 4,664	$ (34,728)	$ (7,911)
Net income (loss) per share, basic	$ (0.21)	$ (0.52)	$ 0.07	$ (0.67)	$ (0.24)
Net income (loss) per share, diluted	$ (0.21)	$ (0.52)	$ 0.06	$ (0.67)	$ (0.24)
Weighted average number of common shares outstanding, basic	88,323,044	73,991,686	63,226,899	51,894,871	33,367,239
Weighted average number of common shares outstanding, diluted	88,323,044	73,991,686	71,919,419	51,894,871	33,367,239

We have derived our statements of operations data for the years ended December 31, 2010 and 2011 and our balance sheet data as of December 31, 2012, 2011 and 2010 from our audited financial statements which are not included in this Annual Report. We have derived our statements of operations data for the years ended December 31, 2014, 2013 and 2012 and our balance sheet data as of December 31, 2014 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).

Supplementary Quarterly Financial Data (Unaudited—In thousands)

	Quarter Ended			
	December 31, 2014	September 30, 2014	June 30, 2014	March 31, 2014
Operating expenses:				
Research and development	$ 1,595	$ 2,385	$ 3,051	$ 3,242
General and administrative	2,249	1,800	1,688	1,829
Total operating expenses	3,844	4,185	4,739	5,071
Operating loss	(3,844)	(4,185)	(4,739)	(5,071)
Other income (expense):				
Interest income	1	2	1	1
Interest expense	(33)	(35)	(35)	(33)
Derivatives gain (loss)	(4,508)	3,005	1,127	—
Other income (expense), net	(4,540)	2,972	1,093	(32)
Net loss	$ (8,384)	$ (1,213)	$ (3,646)	$ (5,103)

	Quarter Ended			
	December 31, 2013	September 30, 2013	June 30, 2013	March 31, 2013
Operating expenses:				
Research and development	$ 3,707	$ 3,021	$ 2,591	$ 1,213
General and administrative	1,968	2,386	2,481	1,638
Total operating expenses	5,675	5,407	5,072	2,851
Operating loss	(5,675)	(5,407)	(5,072)	(2,851)
Other income (expense):				
Interest income	2	4	6	3
Interest expense	(34)	(34)	(33)	(29)
Modification of warrants	—	—	(765)	—
Derivatives loss	—	—	(8,422)	(10,449)
Other expense, net	(32)	(30)	(9,214)	(10,475)
Net loss	$ (5,707)	$ (5,437)	$ (14,286)	$ (13,326)

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

The following discussion should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. The following 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 on Form 10-K.

Introduction

This Management's Discussion and Analysis of our financial condition and results of operations are based on our 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.

Business Overview

We are a research and clinical-stage biomaterials and biotechnology company with a focus on treatment of spinal cord injuries. Our proprietary technologies incorporate intellectual property licensed under an exclusive, world-wide license from Boston Children's Hospital ("BCH") and the Massachusetts Institute of Technology ("MIT"), and intellectual property that has been developed internally, including in collaboration with our advisors and partners. We intend to leverage our platform technology to develop our novel Neuro-Spinal Scaffold, an investigational bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord contusion and is intended to treat acute SCI. We believe our Neuro-Spinal Scaffold will be the foundation of effective therapy for both acute and chronic SCI, and we are continually evaluating other technologies and therapeutics that may be complementary and that offer the potential to bring us closer to our goal of redefining the life of the SCI patient.

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 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. While we are currently focused on advancing our Neuro-Spinal Scaffold, our future R&D expenses will depend on the determinations we make as to the scientific and clinical prospects of each product candidate, 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.

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 in the Notes to Consolidated Financial Statements. Of those policies, we believe that the policies discussed below may involve a higher degree of judgment and may be more critical to an accurate reflection of our financial condition and results of operations.

Share-Based Compensation

Stock options are 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 our 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 departure within the valuation model. The expected term of options granted under our 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. See Note 13, "Stock Options," in the Notes to Consolidated Financial Statements in Item 8 of this Annual Report on Form 10-K for more information about the assumptions underlying these estimates.

Derivative Instruments

Certain of our issued and outstanding warrants to purchase Common Stock contain anti-dilution provisions. These warrants do not meet the requirements for classification as equity and are recorded as derivative warrant liabilities. We 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 Note 12, "Derivative Instruments" in the Notes to Consolidated Financial Statements in Item 8 of this Annual Report on Form 10-K in estimating the fair value for these warrants. Such derivative warrant liabilities are initially recorded at fair value with subsequent changes in fair value charged (credited) to operations in each reporting period. The fair value of the derivative warrant liability is most sensitive to changes in the fair value of the underlying Common Stock and the estimated volatility of our Common Stock.

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.

Recent Accounting Pronouncements

In June 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2014-10, "Development Stage Entities", Topic 915. The objective of the ASU is to improve financial reporting by reducing the cost and complexity associated with the incremental reporting requirements for development stage entities. The ASU removes Topic 915, Development Stage Entities in its entirety from FASB Accounting Standards Codification ("ASC"). The ASU removes all incremental financial reporting requirements from U.S. GAAP for development stage entities, including the inception-to-date information and certain other disclosures. It also eliminates the guidance in ASC 810 on how to assess whether a development stage entity has sufficient equity at risk in the evaluation of whether the development stage entity is a variable interest entity. Additionally, the ASU clarifies that all entities, including entities that have not begun operations, should provide the risk and uncertainty disclosures required in ASC 275. We have elected to early adopt as permitted by ASU 2014-10 and, therefore, have omitted the incremental development stage reporting requirements.

Results of Operations

Comparison of the Years Ended December 31, 2014 and 2013 (in thousands, except share and per share amounts)

Research and Development Expenses

Research and development expenses, as reported, decreased by $260 to $10,273 for the year ended December 31, 2014 from $10,533 for the year ended December 31, 2013. After adjusting for the insurance settlements related to business interruption, ($621 for 2014 and $1,100 for 2013), the research and development expenses were $10,894 and $11,633 for 2014 and 2013 respectively. The decrease in adjusted research and development expenses for 2014 of $739 is primarily attributable to lower compensation and stock compensation expenses of $777 related to the reduction in force during the second quarter of 2014, lower consulting costs of $190, reduction in lab supplies of $142, and other various expenses of $23 which were partly offset by increases in our clinical trial costs of $347.

General and Administrative Expenses

General and administrative expenses decreased by $906 to $7,566 for the year ended December 31, 2014 from $8,472 for the year ended December 31, 2013. The decrease in general and administrative

expenses for 2014 is primarily attributable to lower travel and entertainment expenses of $341, lower recruiting fees of $329, lower facilities costs of $216, lower consulting expenses of $159 and lower donation expenses of $100 and a decrease in other various expenses of $140. These cost reductions were partly offset by higher stock compensation expense of $252 and higher insurance premiums of $127.

Interest Expense

Interest expense increased by $6 to $136 for the year ended December 31, 2014 from $130 for the year ended December 31, 2013. The increase in interest expense is due to an increase in borrowing under the loans payable.

Derivatives Gain (Loss)

Derivative losses decreased by $18,495 to a loss of $376 for the year ended December 31, 2014 from a loss of $18,871 for the year ended December 31, 2013. The 2014 loss of $376 reflects the increase in the fair value of derivative warrant liability which is due primarily to the increase in the fair value of the underlying Common Stock. The 2013 loss of $18,871 was related to the redemption of the investor warrants from offerings prior to 2013.

Loss from Modification of Warrants

The loss from modification of warrants was $765 for the year ended December 31, 2013. No such modification occurred in the year ended December 31, 2014.

Comparison of the Years Ended December 31, 2013 and 2012 (in thousands, except share and per share amounts)

Research and Development Expenses

Research and development expenses increased by $4,157 to $10,533 for the year ended December 31, 2013 from $6,376 for the year ended December 31, 2012. The increase for 2013 is primarily attributable to increased research and development activities, which resulted in increased compensation costs of $1,447 due to additional staffing and salary increases, an increase in stock option expense of $1,693, an increase in rent and facility costs of $605, and higher pre-clinical testing costs of $880 and other various expenses of $632. The 2013 research and development expenses were favorably impacted by insurance payments related to business interruption claims of $1,100.

General and Administrative Expenses

General and administrative expenses increased by $2,069 to $8,472 for the year ended December 31, 2013 from $6,403 for the year ended December 31, 2012. The increase in expenses for 2013 is primarily attributable to higher legal costs of $1,179, an increase in compensation costs related to staffing and salary increases of $391, an increase in stock compensation costs of $210 and an increase in rent and facilities costs of $344. Such expenses were partly offset by a reduction in other spending in the amount of $55.

Interest Expense

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

Derivatives Gain (Loss)

Derivatives loss increased by $36,351 to a loss of $18,871 for the year ended December 31, 2013 from a gain of $17,480 for the year ended December 31, 2012. The increase in this non-cash loss during the year ended December 31, 2013 reflected 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

The loss from modification of warrants was $765 for the year ended December 31, 2013, and is attributable to an increase in the fair value of warrants that resulted from the modification of the terms of warrants in May 2013.

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. At December 31, 2014, our accumulated deficit was $100,255.

At December 31, 2014, we had total assets of $16,693 and total liabilities of $10,775, resulting in stockholders' equity of $5,918, and had a net loss of $18,346. 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 also expect that we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements

Since our inception, we have historically financed our operations primarily through the sale of equity-related securities. At December 31, 2014, our consolidated cash balance was $13,459. In January 2015, we closed a registered direct offering of an aggregate of 8 million shares of our common stock, resulting in net proceeds of approximately $11 million. We believe our current cash and cash equivalents are adequate to fund our operations into the fourth quarter of 2016.

Net cash used in operating activities for the year ended December 31, 2014 was $15,284, and the most significant drivers of which were our net loss of $18,346 and offsetting non-cash stock share based compensation of $2,730.

Net cash used in investing activities for the year ended December 31, 2014 totaled $2 for purchases and disposals of capital equipment.

Net cash provided by financing activities for the year ended December 31, 2014 was $14,765, due mainly to proceeds from the issuance of common stock and warrants of $14,618.

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.

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.

Off Balance Sheet Arrangements

We do not have any 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.

Contractual Obligations

The following summarizes our significant contractual obligations at December 31, 2014, and the effects such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due				
Contractual Obligations	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Long-term debt	$ 1,920	$ 320	$ 1,280	$ 320	$ —
Operating lease payments	4,856	1,243	3,613	—	—
Total	$ 6,776	$ 1,563	$ 4,893	$ 320	$ —

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

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-earning assets consist of cash and cash equivalents of $13,459, or 81% of our total assets at December 31, 2014, and $13,980, or 82% of our total assets at December 31, 2013. Interest income earned on these assets was $5 in 2014 and $15 in 2013. Our interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates. At December 31, 2014, our cash equivalents were primarily composed of money market accounts comprised of U.S. Treasury debt securities and repurchase agreements.

Item 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Consolidated Financial Statements

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, 2014 and 2013, 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, 2014. 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, 2014 and 2013, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

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, 2014, 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 11, 2015 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 11, 2015

InVivo Therapeutics Holdings Corp.

Consolidated Balance Sheets

(In thousands, except share and per-share data)

	December 31,	
	2014	2013
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 13,459	$ 13,980
Restricted cash	422	602
Prepaid expenses and other current assets	1,072	20
Total current assets	14,953	14,602
Property and equipment, net	1,605	2,337
Other assets	135	157
Total assets	$ 16,693	$ 17,096
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 569	$ 899
Loan payable-current portion	320	—
Note payable-current portion	18	74
Capital lease payable	—	3
Derivative warrant liability	7,224	—
Accrued expenses	1,044	1,292
Total current liabilities	9,175	2,268
Loan payable-less current portion	1,600	1,920
Note payable-less current portion	—	18
Total liabilities	10,775	4,206
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.00001 par value, authorized—200,000,000 shares; issued and outstanding—93,812,000 and 78,773,736 shares at December 31, 2014 and 2013, respectively	1	1
Additional paid-in capital	106,172	94,798
Accumulated deficit	(100,255)	(81,909)
Total stockholders' equity	5,918	12,890
Total liabilities and stockholders' equity	$ 16,693	$ 17,096

See notes to the consolidated financial statements.

InVivo Therapeutics Holdings Corp.

Consolidated Statements of Operations

(In thousands, except share and per-share data)

	Years Ended December 31,		
	2014	2013	2012
Operating expenses:			
Research and development	$ 10,273	$ 10,533	$ 6,376
General and administrative	7,566	8,472	6,403
Total operating expenses	17,839	19,005	12,779
Operating loss	(17,839)	(19,005)	(12,779)
Other income (expense):			
Interest income	5	15	35
Interest expense	(136)	(130)	(72)
Modification of warrants	—	(765)	—
Derivative gain (loss)	(376)	(18,871)	17,480
Other income (expense), net	(507)	(19,751)	17,443
Net income (loss)	$ (18,346)	$ (38,756)	$ 4,664
Net income (loss) per share, basic	$ (0.21)	$ (0.52)	$ 0.07
Net income (loss) per share, diluted	$ (0.21)	$ (0.52)	$ 0.06
Weighted average number of common shares outstanding, basic	88,323,044	73,991,686	63,226,899
Weighted average number of common shares outstanding, diluted	88,323,044	73,991,686	71,919,419

See notes to the consolidated financial statements.

InVivo Therapeutics Holdings Corp.

Consolidated Statements of Changes in Stockholders' Equity (Deficit)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance as of December 31, 2011	53,760,471	1	16,657	(47,817)	(31,159)
Share-based compensation expense	—	—	1,233	—	1,233
Issuance of common stock in public offering	9,523,810	—	18,155	—	18,155
Issuance of common stock for services	15,000	—	25	—	25
Issuance of common stock upon exercise of warrants	1,779,716	—	1,129	—	1,129
Issuance of common stock upon exercise of stock options	755,020	—	111	—	111
Issuance of common stock to 401(k) plan	47,105	—	91	—	91
Fair value of warrants issued for services	—	—	32	—	32
Fair value of derivative warrant liability reclassified to additional paid-in capital	—	—	3,409	—	3,409
Net income	—	—	—	4,664	4,664
Balance as of December 31, 2012	65,881,122	1	40,842	(43,153)	(2,310)
Share-based compensation expense	—	—	3,136	—	3,136
Issuance of common stock upon exercise of warrants	12,224,846	—	15,952	—	15,952
Issuance of common stock upon exercise of stock options	588,884	—	455	—	455
Issuance of common stock to 401(k) plan	78,884	—	192	—	192
Fair value of derivative warrant liability reclassified to additional paid-in capital	—	—	33,456	—	33,456
Incremental fair value from warrant modification	—	—	765	—	765
Net loss	—	—	—	(38,756)	(38,756)
Balance as of December 31, 2013	78,773,736	1	94,798	(81,909)	12,890
Share-based compensation expense	—	—	2,730	—	2,730
Issuance of common stock in public offering	14,001,250	—	7,770	—	7,770
Issuance of common stock					

for services	298,505	—	477	—	477
Issuance of common stock upon exercise of warrants	39,900	—	12	—	12
Issuance of common stock upon exercise of stock options	531,598	—	212	—	212
Issuance of common stock to 401(k) plan	167,011	—	173	—	173
Net loss	—	—	—	(18,346)	(18,346)
Balance as of December 31, 2014	93,812,000	1	106,172	(100,255)	5,918

See notes to the consolidated financial statements.

InVivo Therapeutics Holdings Corp.

Consolidated Statements of Cash Flows

(In thousands)

	Years Ended December 31,		
	2014	2013	2012
Cash flows from operating activities:			
Net income (loss)	$ (18,346)	$ (38,756)	$ 4,664
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization expense	752	740	367
Non-cash derivative (gain) losses	376	18,871	(17,480)
Non-cash interest expense	—	—	22
Non-cash loss from modification of warrants	—	765	—
Common stock issued to 401(k) plan	173	192	92
Common stock issued for services	477	—	25
Share-based compensation expense	2,730	3,136	1,233
Changes in operating assets and liabilities:			
Restricted cash	180	—	(54)
Prepaid expenses	(363)	124	(61)
Insurance receivable	(689)	—	—
Other assets	4	5	—
Accounts payable	(330)	(254)	585
Accrued expenses	(248)	271	403
Net cash used in operating activities	(15,284)	(14,906)	(10,204)
Cash flows from investing activities:			
Non-cash disposals of property and equipment	45	—	—
Purchases of property and equipment	(47)	(749)	(2,141)
Net cash used in investing activities	(2)	(749)	(2,141)
Cash flows from financing activities:			
Proceeds from exercise of stock options	212	456	111
Proceeds from exercise of warrants, net	12	15,952	1,129
Proceeds from issuance of note payable	—	150	—
Repayment of note payable	(56)	(57)	—
Principal payments on capital lease obligation	(21)	(33)	(33)
Proceeds from loans payable	—	342	1,747
Repayment of loans payable	—	—	(303)
Proceeds from issuance of common stock and warrants	14,618	—	18,155
Net cash provided by financing activities	14,765	16,810	20,806
Increase (decrease) in cash and cash equivalents	(521)	1,155	8,461
Cash and cash equivalents at beginning of period	13,980	12,825	4,364
Cash and cash equivalents at end of period	$ 13,459	$ 13,980	$ 12,825
Supplemental disclosure of cash flow information and non-cash investing and financing activities:			
Cash paid for interest	$ 132	$ 125	$ 50
Fair value of warrants issued in connection with underwriting agreement	$ 6,848	$ —	$ —
Fair value of warrants issued in connection with loan agreement	$ —	$ —	$ 32
Reclassification of derivative warrant liability to additional paid-in capital	$ —	$ 33,456	$ 3,409

See notes to the consolidated financial statements.

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements

(In thousands, except share and per-share data)

1. NATURE OF OPERATIONS

Business

InVivo Therapeutics Corporation ("InVivo") is a pioneering biomaterials and biotechnology company with a focus on the treatment of spinal cord injuries. Its proprietary technologies incorporate intellectual property that is licensed under an exclusive, world-wide license from Boston Children's Hospital and the Massachusetts Institute of Technology, as well as intellectual property that has been developed internally in collaboration with its 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.

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.

Basis of presentation and 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 that 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, 2014 and 2013, cash equivalents were comprised of money market funds. The Company had no marketable investments at December 31, 2014 and 2013.

Cash and cash equivalents consist of the following:

	December 31,	
	2014	2013
Cash on deposit	$ 269	$ 219
Money market fund	13,190	13,761
Total cash and cash equivalents	$ 13,459	$ 13,980

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements (Continued)

(In thousands, except share and per-share data)

2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

Restricted cash

At December 31, 2014 and 2013, the restricted cash of $422 and $602, respectively, represents a $111 and $291, respectively, security deposit related to the Company's credit card account, and, for each year, a $311 standby letter of credit in favor of a landlord (see Note 17).

Financial instruments

The carrying amounts reported in the Company's 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 and amortization 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 and amortization expense for the years ended December 31, 2014, 2013, and 2012 was $752, $740 and $367, respectively. Maintenance and repairs are charged to expense as incurred, while any additions or improvements are capitalized. During 2014, the Company had disposals of $47.

Research and development expenses

Costs incurred for research and development are expensed as incurred.

Concentrations of credit risk

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, 2014 and 2013, all of the Company's assets were located in the United States.

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements (Continued)

(In thousands, except share and per-share data)

2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

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, 2014 or 2013. Tax years subsequent to 2010 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, 2014, 2013 and 2012.

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 Company's 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.

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

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements (Continued)

(In thousands, except share and per-share data)

2. SIGNIFICANT ACCOUNTING POLICIES (Continued)

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 June 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") 2014-10, "Development Stage Entities", Topic 915. The objective of the ASU is to improve financial reporting by reducing the cost and complexity associated with the incremental reporting requirements for development stage entities. The ASU removes Topic 915, Development Stage Entities in its entirety from FASB Accounting Standards Codification ("ASC"). The ASU removes all incremental financial reporting requirements from U.S. GAAP for development stage entities, including the inception-to-date information and certain other disclosures. It also eliminates the guidance in ASC 810 on how to assess whether a development stage entity has sufficient equity at risk in the evaluation of whether the development stage entity is a variable interest entity. Additionally, the ASU clarifies that all entities, including entities that have not begun operations, should provide the risk and uncertainty disclosures required in ASC 275. The Company has elected to early adopt as permitted by ASU 2014-10 and, therefore, has omitted inception-to-date information and certain other disclosures.

3. PROPERTY AND EQUIPMENT

Property and equipment, net consisted of the following:

	2014	2013
Computer software and hardware	$ 562	$ 560
Research and lab equipment	1,873	1,881
Leasehold improvements	390	381
Office Equipment	790	791
Less accumulated depreciation and amortization	(2,010)	(1,276)
Property and equipment, net	$ 1,605	$ 2,337

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements (Continued)

(In thousands, except share and per-share data)

4. INTANGIBLE ASSETS

Intangible assets, included in "other assets," consisted of patent licensing fees paid to license intellectual property (see Note 16). The Company is amortizing the license fee as a research and development expense over the 15-year term of the license.

	2014	2013
Patent licensing fee	$ 200	$ 200
Accumulated amortization	(86)	(69)
	$ 114	$ 131

For each of the years ended December 31, 2014, 2013, and 2012, the amortization expense was $18. Amortization expense in each of the next five years is also expected to be $18 per year.

5. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	December 31,	
	2014	2013
Accrued bonus	$ —	$ 566
Accrued payroll	49	101
Deferred rent payable	505	553
Accrued vacation	72	23
Accrued legal	360	—
Other accrued expenses	58	49
	$ 1,044	$ 1,292

6. NOTE PAYABLE

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

Pursuant to the terms of this non-cancelable purchase agreement in effect at December 31, 2014, the future minimum principal payments are as follows:

Year Ended December 31,	
2015	18
Total	$ 18

In the third quarter of 2013, the Company decided to abandon the implementation of the ERP system. As such, the ERP system cost of $150 was fully expensed in 2013. The Company reserves the right to implement the ERP system at a future date.

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements (Continued)

(In thousands, except share and per-share data)

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.

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

	At December 31, 2014			
	Level 1	Level 2	Level 3	Fair Value
Liabilities:				
Derivative warrant liability	$ —	$ 7,224	$ —	$ 7,224

There were no assets or liabilities measured at fair value on a recurring basis at December 31, 2013, and there were no assets or liabilities measured at fair value on a non-recurring basis at December 31, 2014 and 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,	
	2014	2013
Capital lease payable	$ —	$ 3
Less: current portion	—	(3)
	$ —	$ —

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements (Continued)

(In thousands, except share and per-share data)

8. CAPITAL LEASE PAYABLE (Continued)

The total value of the laboratory equipment acquired under this capital lease agreement was $124 including a down payment of $31. The capital lease is payable in monthly installments of $3 payable over thirty-six months and the final payment was made in January 2014. For the years ended December 31, 2014 and 2013, interest expense recorded on the capital lease was $0 and $1, respectively. For each of the years ended December 31, 2014, 2013 and 2012, depreciation expense on the assets under capital lease was $25. The net book value at December 31, 2014 and 2013 amounted to $27 and $52, respectively.

9. LOAN PAYABLE

In October 2012, the Company entered into a loan agreement with the Massachusetts Development Finance Agency ("MassDev"). The loan agreement provided the Company with a $2,000 line of credit from the Commonwealth of Massachusetts's Emerging Technology fund, with $200 to be used for working capital purposes and the remainder to be used for the purchase of capital equipment. The annual interest rate is fixed at 6.5% with interest-only payments for the first thirty months, commencing on November 1, 2012, and then equal interest and principal payments over the next fifty-four months, with the final maturity of the loan on October 5, 2019. Based on the $1,920 balance outstanding as of December 31, 2014, equal monthly principal payments of $36 will be due commencing on May 1, 2015. Therefore, for the years ending December 31, 2015, 2016, 2017, 2018, and 2019, principal payments of $320, $427, $426, $427, and $320, respectively, will be due. In September 2012, the Company was assessed commitment fees totaling $15, which was charged to the Company as 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 its 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 $32 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 years ended December 31, 2014 and 2013 was $5, and was included in interest expense in the Company's consolidated statements of operations. 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, for capital equipment. Interest expense related to this loan was $127 for the year ended December 31, 2014 and $120 for the year ended December 31, 2013.

In June 2011, the Company entered into a loan agreement with a bank for a $1,000 line of credit used for the purchase of certain capital equipment. The annual interest rate was the greater of 6.75% or 3.50% above the prime rate as set forth in the agreement. Borrowings were repayable in equal monthly installments over a thirty-six month period. The Company was assessed commitment fees totaling $10 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 $10, 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 due to the bank and wrote off the remaining deferred financing costs. Amortization of deferred financing costs on this loan for the year ended December 31, 2012 was $6, and was included in interest expense. Interest expense related to the loan payable to the bank was $16 for the year ended December 31, 2012.

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements (Continued)

(In thousands, except share and per-share data)

9. LOAN PAYABLE (Continued)

At December 31, loans payable consisted of the following:

	December 31, 2014	December 31, 2013
Equipment Loan	$ 1,920	$ 1,920
Less: current portion	320	—
	$ 1,600	$ 1,920

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, 2014, the Company had U.S. federal and Massachusetts net operating loss carryforwards of $58,293 and $50,568, 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 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, 2014 of $867 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, 2014	December 31, 2013
Net operating loss carryforward	$ 22,490	$ 16,032
Research and development credit carryforward	801	625
Stock-based compensation	2,265	2,411
Depreciation and amortization	(124)	(149)
Accrued expenses	226	449
Charitable contributions	112	112
Subtotal	25,770	19,480
Valuation allowance	(25,770)	(19,480)
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, 2014 and 2013, the valuation allowance increased by $6,290 and $7,738, respectively.

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements (Continued)

(In thousands, except share and per-share data)

10. INCOME TAXES (Continued)

The Company has no uncertain tax positions at December 31, 2014 and 2013 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 U.S. federal and state income tax examinations by tax authorities for all years for which a loss carryforward is available.

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

	December 31,		
	2014	2013	2012
Statutory rate	(34.0)%	(34.0)%	34.0%
State taxes, net of benefit	(4.8)%	(2.6)%	(14.2)%
Permanent differences:			
Derivative losses	0.7%	17.1%	(127.4)%
Other	2.6%	0.0%	(1.9)%
R&D tax credit	(1.0)%	(0.4)%	7.0%
True up, past year	2.2%	0.0%	0.0%
Increase in valuation reserve	34.3%	19.9%	102.5%
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 93,812,000, shares were issued and outstanding as of December 31, 2014 and 78,773,736 shares were issued and outstanding as of December 31, 2013.

During the year ended December 31, 2014, the Company issued an aggregate of 531,598 shares of Common Stock upon the exercise of stock options and received cash proceeds of $212.

During the year ended December 31, 2014, the Company issued an aggregate of 39,900 shares of Common Stock upon the exercise of warrants, including warrants to purchase 62,620 shares of Common Stock exercised through cashless exercise provisions resulting in the issuance of 27,610 shares of common stock and warrants to purchase 12,290 shares of Common Stock exercised for cash, providing cash proceeds of $12.

During the year ended December 31, 2014, the Company issued an aggregate of 167,011 shares of Common Stock with a fair value of $173 to the Company's 401(k) plan as a matching contribution.

In January 2014, the Company issued 108,848 and 22,374 shares of Common Stock to Michael J. Astrue, the Company's then-Interim Chief Executive Officer, and Gregory D. Perry, the Company's then-Interim Chief Financial Officer, respectively, in lieu of executive cash bonuses. Such shares had an aggregate fair value of approximately $282.

In December 2014, the Company issued 167,283 shares of Common Stock to certain employees of the Company in lieu of cash bonuses. Such shares had an aggregate fair value of approximately $195.

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements (Continued)

(In thousands, except share and per-share data)

11. COMMON STOCK (Continued)

During the year ended December 31, 2014, the Company closed an underwritten public offering of an aggregate of 14,001,250 shares of common stock and warrants to purchase up to an aggregate of 7,000,625 shares of common stock, at a price to the public of $1.15 per share of common stock and $0.00001 per warrant. The net proceeds to the Company, after deducting underwriting discounts and offering expenses, were approximately $14,600. The warrants have a per share price of $1.4375, or 125% of the public offering of the common stock, and expire on May 9, 2019.

During the year ended December 31, 2013, the Company issued an aggregate of 588,884 shares of Common Stock upon the exercise of stock options and received cash proceeds of $456.

During the year ended December 31, 2013, the Company issued an aggregate of 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 $15,952.

During the year ended December 31, 2012, the Company issued 15,000 unregistered shares of Common Stock with a fair value of $25 to an investor relations firm in exchange for services provided.

During the year ended December 31, 2012, the Company issued an aggregate of 755,020 shares of Common Stock upon the exercise of stock options and received cash proceeds of $111.

During the year ended December 31, 2012, the Company issued an aggregate of 1,779,716 shares of Common Stock upon the exercise of warrants, including warrants to purchase 1,865,670 shares of Common Stock exercised through cashless exercise provisions and warrants to purchase 852,946 shares of Common Stock exercised for cash, providing cash proceeds of $1,129.

During the year ended December 31, 2012, the Company completed a public offering of Common Stock and issued 9,523,810 shares of its Common Stock at a purchase price of $2.10 per share. The offering raised gross proceeds of approximately $20,000, and the Company received net proceeds of $18,155, after deducting underwriter discounts and offering expenses.

Common Stock Reserves

As of December 31, 2014, the Company had the following reserves established for the future issuance of Common Stock as follows:

Reserves for the exercise of warrants	10,208,849
Reserves for the exercise of stock options	12,361,445
Total Reserves	22,570,294

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 was reclassified from Derivative warrant liability to Additional paid-in capital related to warrants

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements (Continued)

(In thousands, except share and per-share data)

12. DERIVATIVE INSTRUMENTS (Continued)

exercised. In May 2013 outstanding investor warrants totaling 11,726,343 warrants, were exercised and the fair value of $25,241was reclassified from Derivative warrant liability to Additional paid-in capital.

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 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 a non-cash charge of $765 which 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 was reclassified from Derivative warrant liability to Additional paid-in capital.

The warrants issued in connection with the May 2014 public offering to purchase 7,000,625 shares of the Common Stock (see Note 11) have anti-dilution protection provisions and, under certain conditions, grant the right to the holder to require the Company to re-price the warrant. Accordingly these warrants are accounted for as derivative liabilities. 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. Changes in fair value of the derivative financial instruments are recognized in the Company's consolidated statement of operations as a derivative gain or loss. The warrant derivative gains (losses) are non-cash income (expenses); and for the 12 months ended December 31, 2014, 2013 and 2012, a gain (loss) of $(376) and $(18,871) and $17,480, respectively, were included in other income (expense) in the Company's consolidated statement of operations.

The Company uses the Black-Scholes option pricing model and assumptions that consider among other factors the fair value of the underlying stock, risk -free interest rate, volatility, expected life and dividend rates in estimating fair value for the warrants considered to be derivative instruments. The fair value of these derivative instruments at December 31, 2014 and 2013 was $7,224 and $0, 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 derivative gain or loss.

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements (Continued)

(In thousands, except share and per-share data)

12. DERIVATIVE INSTRUMENTS (Continued)

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

	Year Ended December 31,		
	2014	2013	2012
Risk free interest rate	1.47%	N/A	0.32 - 0.35%
Expected dividend yield	0%	N/A	0%
Contractual term	4.4 years	N/A	2.7 - 2.9 years
Expected volatility	119%	N/A	73%

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

The table below presents the changes in derivative warrant liability during the years ended December 31, 2014, 2013, and 2012:

	Year Ended December 31,		
	2014	2013	2012
Balance at beginning of year	$ —	$ 14,585	$ 35,473
Issuance of warrants	6,848	—	—
Increase (decrease) in the fair value of the warrants	376	18,871	(17,480)
Fair value of derivative warrant liability reclassified to additional paid in capital	—	(33,456)	(3,408)
Balance at end of year	$ 7,224	$ —	$ 14,585

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, 2014, an aggregate of 1,692,309 shares of Common Stock were outstanding under the 2007 Plan and no shares were 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 (as subsequently amended, 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, 2014, the number of shares authorized for issuance under the 2010 Plan, as amended, was 11,000,000 shares. As of December 31, 2014, an aggregate of 8,753,353 shares of Common Stock were outstanding under the 2010 Plan and 1,748,500 shares were 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.

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements (Continued)

(In thousands, except share and per-share data)

13. STOCK OPTIONS (Continued)

Share-based compensation

For stock options issued and outstanding for the years ended December 31, 2014, 2013 and 2012, the Company recorded non-cash, stock-based compensation expense of $2,730, $3,136 and $1,233, 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.

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

	December 31,		
	2014	2013	2012
Risk-free interest rate	1.62 - 2.06%	0.77 - 2.52%	0.62 - 1.23%
Expected dividend yield	0%	0%	0%
Expected term (employee grants)	6.03 years	6.25 years	6.25 years
Expected volatility	124%	102%	75%

A summary of option activity as of December 31, 2014 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, 2013	8,055,522	$ 1.55		
Granted	4,711,250	$ 1.75		
Forfeited	(1,770,948)	$ 1.86		
Exercised	(550,162)	$ 0.42		
Outstanding at December 31, 2014	10,445,662	$ 1.65	7.61	$ 2,569
Vested at December 31, 2014	3,960,662	$ 1.28	5.16	$ 1,986

The weighted average grant-date fair value of options granted during years ended December 31, 2014, 2013 and 2012 was $1.54, $2.04, and $1.28 per share, respectively. The total fair value of options that vested in years ended December 31, 2014, 2013, and 2012 was $2,329, $1,985 and $1,186, respectively. As of December 31, 2014, there was $5,750 of total unrecognized compensation expense,

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements (Continued)

(In thousands, except share and per-share data)

13. STOCK OPTIONS (Continued)

related to non-vested share-based option compensation arrangements. The unrecognized compensation expense is estimated to be recognized over a period of 2.91 years at December 31, 2014.

14. WARRANTS

The following table presents information about warrants to purchase Common Stock issued and outstanding at December 31, 2014:

Year Issued	Classification	Number of Warrants	Exercise Price	Date of Expiration
2010	Equity	1,494,603	$ 1.40	10/26/2017 - 12/3/2017
2010	Equity	1,318,268	$ 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
2014	Liability	7,000,625	$ 1.44	5/9/2019
Total		10,208,849		
Weighted average exercise price			$ 1.43	
Weighted average life in years				3.81

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, 2014, 2013 and 2012, the Company made matching contributions in the form of shares of Common Stock. For the years ended December 31, 2014, 2013, and 2012, the Company issued 167,011, 78,884, and 47,105 shares of Common Stock, respectively, with related fair values of $173, $192, and $92, respectively, were recorded as expense in the statement of operations.

16. INTELLECTUAL PROPERTY LICENSE

In July 2007, the Company entered into a world-wide exclusive license (the "BCH License") for patents co-owned by BCH and MIT 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 BCH License was amended, and the Company obtained additional rights for use in the field of peripheral nerve injuries. The BCH License, as amended, 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, under certain conditions as defined in the related license agreement. In connection with the BCH License, the Company paid an initial $75 licensing fee and is required to pay certain annual maintenance fees, milestone payments and royalties. During 2011, the Company paid $75 to expand the license and, at December 31, 2011, accrued $50 for a milestone payment. License fees and milestone payments are capitalized and total $200 at December 31, 2014 (see Note 4). Maintenance and royalty costs are expensed as incurred.

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements (Continued)

(In thousands, except share and per-share data)

17. COMMITMENTS AND CONTINGENCIES

Leases

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, Massachusetts (as amended, the "Cambridge Lease"). The term of the Cambridge Lease is six years and three months, with one five-year extension option. The terms of the Cambridge Lease require a standby letter of credit in the amount of $311 (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 term of the Cambridge Lease and records the difference between the amount charged to expense and the rent paid as a deferred rent liability. As of December 31, 2014, the amount of deferred rent liability is $505 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. In connection with the Cambridge Lease, the Company paid for lessor assets and was not reimbursed through construction allowances. Such costs are recorded as leasehold improvements, which are amortized to rent expense over the term of the Cambridge Lease. As of December 31, 2014, such leasehold improvements totaled $390 and are $249, net of accumulated depreciation.

Pursuant to the terms of the non-cancelable lease agreements in effect at December 31, 2014, the future minimum rent commitments are as follows:

Year Ended December 31,	
2015	$ 1,243
2016	1,269
2017	1,295
2018	1,049
Total	$ 4,856

Total rent expense for the years ended December 31, 2014, 2013, and 2012, including month-to-month leases, was $1,148, $1,125 and $758, respectively.

On September 4, 2013, the Company entered into a legal settlement agreement for $286, in connection with the Cambridge Lease. The settlement has been included in the deferred rent liability and the benefit will be amortized over the remainder of the term of the Cambridge Lease.

Litigation

Lawsuit with Former Employee

In November 2013, we filed a lawsuit against Francis Reynolds, our 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 monetary damages and an accounting. The lawsuit involves approximately $500 worth of personal and/or exorbitant expenses that we allege

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements (Continued)

(In thousands, except share and per-share data)

17. COMMITMENTS AND CONTINGENCIES (Continued)

Mr. Reynolds inappropriately caused us to pay while he was serving as our Chief Executive Officer, Chief Financial Officer, President and Chairman of our Board of Directors. On December 6, 2013, Mr. Reynolds answered the complaint, and filed counterclaims against us and our 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 we 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, we, along with the directors named in the counterclaims, filed our answer. The parties are currently conducting pre-trial discovery. No judgments or rulings are pending at this stage.

Shareholder Matters and Investigations

On July 31, 2014, a putative securities class action lawsuit was filed in the United States District Court for the District of Massachusetts, naming the Company and Mr. Reynolds, as defendants (the "Securities Class Action"). The lawsuit alleges violations of the Securities Exchange Act of 1934 in connection with allegedly false and misleading statements related to the timing and completion of the clinical study of the Company's Neuro-Spinal Scaffold. The plaintiff seeks class certification for purchasers of the Company's common stock during the period from April 5, 2013 through August 26, 2013 and unspecified damages. On December 12, 2014, the Company moved to dismiss this lawsuit, and a hearing on that motion is scheduled for March 11, 2015. The Company intends to vigorously defend the lawsuit.

On January 23, 2015, Shawn Luger, a purported shareholder of the Company, sent the Company a letter demanding that the Board of Directors take action to remedy purported breaches of fiduciary duties allegedly related to the claimed false and misleading statements that are the subject of the Securities Class Action (the "Shareholder Demand"). The Board of Directors is currently considering this demand.

In addition to the Securities Class Action and the Shareholder Demand, the Company has received investigation subpoenas from the Boston Regional Office of the Securities and Exchange Commission and the Massachusetts Securities Division of the Secretary of the Commonwealth of Massachusetts requesting corporate documents also concerning, among other topics, the allegations raised Securities Class Action and the Shareholder Demand. The Company is currently cooperating with these investigations.

18. INSURANCE CLAIM

During the year ended December 31, 2014, the Company settled an insurance claim of $621 for business interruption that covered the disruption of the Company's operations at its facility in Cambridge, Massachusetts caused by water damage that occurred in September 2014. The insurance settlement reimburses the Company for costs incurred as a result of the disruption and is included as reduction of research and development expense in the consolidated statement of operations for the year ended December 31, 2014. The settlement receivable is included in other current asset in the 2014 financial statements.

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements (Continued)

(In thousands, except share and per-share data)

18. INSURANCE CLAIM (Continued)

During the year ended December 31, 2013, the Company received insurance proceeds of approximately $1,100 from the settlement of a business interruption claim that covered the disruption of the Company's operations at its facility in Cambridge, Massachusetts 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.

19. SUBSEQUENT EVENTS

In January 2015, the Company closed a registered direct offering of an aggregate of 8 million shares of common stock, resulting in net proceeds of approximately $11,000.

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 ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is (i) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and (ii) 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 13a 15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2014, 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 of 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, 2014 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, 2014.

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 is also based, in part. upon certain assumptions about the likelihood of future 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, 2014, 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

Wolf & Company, P.C., 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, which is included herein.

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, 2014, 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, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, 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 the Company as of December 31, 2014 and 2013, 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, 2014, and our report dated March 11, 2015, expressed an unqualified opinion.

/s/ Wolf & Company, P.C.

Boston, Massachusetts
March 11, 2015

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 2015 Annual Meeting of Stockholders.

Code of Ethics

We previously adopted a Code of Business Conduct and Ethics that applies to all employees, officers and directors of our Company, including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. Our Code of Business Conduct and Ethics is available in the "Investor Relations" section of our website at www.invivotherapeutics.com. A copy of our Code of Business Conduct and Ethics can also be obtained free of charge by contacting our Secretary, c/o InVivo Therapeutics Holdings Corp., One Kendall Square, Suite B14402, Cambridge, Massachusetts 02139. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics by posting such information on our website.

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 2015 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 2015 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 2015 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 2015 Annual Meeting of Stockholders.

PART IV

Item 15. EXHIBITS, 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.

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 11, 2015

By: /s/ STEVEN F. MCALLISTER

Name: Steven F. McAllister
Title: *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
/s/ MARK D. PERRIN Mark D. Perrin	Chief Executive Officer and Chairman of the Board (Principal Executive Officer)	March 11, 2015
/s/ STEVEN F. MCALLISTER Steven F. McAllister	Chief Financial Officer (Principal Financial and Accounting Officer)	March 11, 2015
/s/ JOHN A. MCCARTHY, JR. John A. McCarthy, Jr.	Director	March 11, 2015
/s/ KENNETH DIPIETRO Kenneth DiPietro	Director	March 11, 2015
/s/ DANIEL R. MARSHAK Daniel R. Marshak	Director	March 11, 2015
/s/ C. ANN MERRIFIELD C. Ann Merrifield	Director	March 11, 2015
/s/ RICHARD J. ROBERTS Richard J. Roberts	Director	March 11, 2015

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).

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 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.
10.3	Form of Subscription Agreement, by and between InVivo Therapeutics Holdings Corp. and the investors in the offering (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on December 9, 2010).
10.4*	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).
10.5(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).
10.5(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).
10.6*	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).
10.7(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).
10.7(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).
10.8	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).

10.9 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).

10.10	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).
10.11	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).
10.12	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).
10.13	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).
10.14	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).
10.15	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).
10.16	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).
10.17*	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).
10.18	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).
10.19*	Employment Agreement, dated as of August 22, 2013, between the Company and Michael J. Astrue (incorporated by reference from Exhibit 10.26 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2013, as filed with the SEC on March 17, 2014).
10.20*	Employment Agreement, dated as of September 16, 2013, between the Company and Gregory D. Perry (incorporated by reference from Exhibit 10.27 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2013, as filed with the SEC on March 17, 2014).
10.21*	Employment Agreement, dated as of December 23, 2013, between the Company and Mark D. Perrin (incorporated by reference from Exhibit 10.28 to the Company's

Annual Report on Form 10-K for the fiscal year ended December 31, 2013, as filed with the SEC on March 17, 2014).

10.22*	Employment Agreement, dated as of December 31, 2013, between the Company and Steven F. McAllister (incorporated by reference from Exhibit 10.29 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2013, as filed with the SEC on March 17, 2014).
10.23*	Amendment to the December 31, 2013 Employment Agreement, dated as of April 29, 2014, between the Company and Steven F. McAllister.
10.24*	Amended and Restated Employment Agreement, dated as of May 30, 2014, between the Company and Steven F. McAllister (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on May 30, 2014).
10.25*	Second Amended and Restated Employment Agreement, dated as of June 17, 2014, between the Company and Steven F. McAllister (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on June 23, 2014).
10.26	Letter Agreement, dated as of December 10, 2014, between the Company and H.C. Wainwright & Co., LLC (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on January 29, 2015).
10.27	Securities Purchase Agreement, dated as of January 28, 2015, between the Company and the purchasers signatory thereto (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K/A, as filed with the SEC on January 29, 2015).
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.