INVIVO THERAPEUTICS HOLDINGS CORP.
Form 10-K
March 10, 2017
Table of Contents

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, 2016
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 001 37350

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:

Title of each class to be so registered	Name of exchange on which registered
Common Stock, $0.00001 par value	The Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act: None.

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, 2016, the last business day of the registrant's most recently completed second fiscal quarter, was $183,453,628 based on a per share price of $5.78, which was the closing price of the registrant's common stock on the Nasdaq Global Market on such date.

As of March 3, 2017, the number of shares outstanding of the registrant's common stock, $0.00001 par value per share, was 32,110,826.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2017 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, 2016.

Table of Contents

INVIVO THERAPEUTICS HOLDINGS CORP.

ANNUAL REPORT ON FORM 10 K

FOR THE YEAR ENDED DECEMBER 31, 2016

TABLE OF CONTENTS

Table of Contents

PART I

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10 K contains "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Statements, other than statements of historical facts, contained in this Annual Report on Form 10 K regarding future events, our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, and objectives of management, are forward looking statements. In some cases, you can identify forward looking statements by terminology such as "may," "might," "will," "should," "intends," "expects," "plans," "goals," "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 2017, the safety, feasibility, and clinical benefit of our Neuro-Spinal Scaffold™ implant, the expected completion of our pivotal probable benefit study of the 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 and to continue as a going concern;
- our ability to obtain regulatory approvals for our products, including our Neuro-Spinal Scaffold;
- our ability to successfully commercialize our current and future product candidates, including our Neuro-Spinal Scaffold;
- 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;
- our reliance on third parties to conduct testing and clinical trials;
- market acceptance of our technology and products;

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

- our ability to attract and retain key personnel; and

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

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

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

Table of Contents

Item 1. BUSINESS

Overview

We are a research and clinical-stage biomaterials and biotechnology company with a focus on treatment of spinal cord injuries ("SCIs"). Our mission is to redefine the life of the SCI patient, and we are developing treatment options intended to provide meaningful improvement in patient outcomes following SCI. Our approach to treating acute SCIs is based on our investigational Neuro-Spinal Scaffold™ implant, a bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord and is intended to treat acute SCI. We believe the Neuro-Spinal Scaffold is the only SCI therapy in development focused solely on treating acute SCI directly at the epicenter of the injury. The Neuro-Spinal Scaffold incorporates intellectual property licensed under an exclusive, worldwide license from Boston Children's Hospital ("BCH") and the Massachusetts Institute of Technology ("MIT"). We are continually evaluating other technologies and therapeutics that may be complementary to our development of the Neuro-Spinal Scaffold or offer the potential to bring us closer to our goal of redefining the life of the SCI patient. We have also entered into exclusive license/assignment agreements with the University of California, San Diego and James Guest, M.D., Ph.D. covering delivery methods and devices for our preclinical Therapeutic Trails™ injection program.

Market Opportunity

Our clinical program is intended to address the lack of successful treatments for SCIs, which can lead to permanent paralysis, sensory impairment, and autonomic (bowel, bladder, and sexual) dysfunction. The current management of acute SCI is a surgical approach consisting of spine stabilization and an external decompression procedure of uncertain value. We believe the market opportunity for our Neuro-Spinal Scaffold implant is significant. It is estimated that approximately 282,000 people are currently living in the United States with paralysis due to SCI (chronic SCI), and approximately 15,000 individuals in the United States will become fully or partially paralyzed each year (acute SCI). We are pursuing regulatory approval from the U.S. Food and Drug Administration ("FDA") through the Humanitarian Device Exemption ("HDE") pathway. When this pathway was initiated for the Neuro-Spinal Scaffold implant, it was limited to populations of 4,000 or less patients per year. We were granted a Humanitarian Use Device ("HUD") designation for the Neuro-Spinal Scaffold, which includes thoracic and cervical patients afflicted with complete (no motor or sensory function in the lowest sacral segments) SCI, such as paraplegia or tetraplegia, and excludes gunshot or other penetrating wounds. Recently, the 21st Century Cures Act increased the upper population limit for an HDE from 4,000 to 8,000, which allows us to potentially request an expansion of our current HUD to include additional SCI patients, i.e., incomplete (partial sensory or sensory/motor function below the injury site, including the lowest sacral segments) SCI patients. Future products, which may include use of stem cells or drug ingredients, may enable the treatment of a broader population such as patients with chronic paralysis and would require separate regulatory approval.

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 SCI statistics. The financial impact of SCIs,

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 in 2016 by NSCISC titled "Spinal Cord Injury—Facts and Figures at a Glance", (i) during the first year, average cost of care ranges from $347,896 to $1,065,980, depending on the severity of the injury, (ii) the net present value ("NPV") to maintain a quadriplegic injured at age 25 for life is $4,729,788, and (iii) the NPV to maintain a paraplegic injured at age 25 for life is $2,312,846. 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.

The American Spinal Injury Association ("ASIA"), in collaboration with the International Spinal Cord Society ("ISCoS"), has developed a neurologic examination tool for assessing SCI known as the International Standards for Neurological Classification of Spinal Cord Injury ("ISNCSCI"). Results of the ISNCSCI examination are used to determine the ASIA Impairment Scale ("AIS") classification.

Patients with complete SCI are classified as AIS A. Patients with incomplete SCI, who have partial sensory and/or motor function below the level of injury, including the lowest sacral segments, are classified as AIS B (partial sensory function), AIS C (partial sensory and motor function), or AIS D (partial sensory and increased motor function,

Table of Contents

i.e., can move at least half of the muscles against gravity). Patients who have a complete return of sensory and motor function are classified as AIS E.

These classifications are based upon the ISNCSCI examination in which an examiner performs a neurologic examination to assess sensory function of the entire body and motor function of the upper and lower extremities.

Our Clinical and Preclinical Programs

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

Neuro-Spinal Scaffold™ implant for acute SCI

Our leading product under development is the Neuro-Spinal Scaffold, an investigational bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord. The Neuro-Spinal Scaffold is intended to promote appositional, or side-by-side, healing by supporting the surrounding tissue after injury, minimizing expansion of areas of necrosis, and providing a biomaterial substrate for the body's own healing/repair processes following injury. We believe this form of appositional healing may spare white matter, increase neural sprouting, and diminish post traumatic cyst formation.

The Neuro-Spinal Scaffold is composed of two biocompatible and bioresorbable polymers that are cast to form a highly porous investigational product:

· 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 to promote cellular attachment.

Because of the complexity of SCIs, it is likely that multi modal therapies will be required 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 FDA, or growth factors.

We expect the Neuro-Spinal Scaffold will be regulated by the FDA as a Class III medical device. See "Government Regulation" below for additional information on the regulatory pathway for the Neuro-Spinal Scaffold.

Preclinical and Non clinical Studies relating to the Neuro-Spinal ScaffoldTM

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 persist 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 preclinical 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. Hemicordectomy injury models, in which sections of spinal cord are surgically removed, are useful in the evaluation of treatment strategies that involve device implantation. Unilateral hemicordectomy 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 hemicordectomy 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.

Our first non clinical study was conducted by founding scientists of our wholly owned subsidiary in rats with surgically induced unilateral spinal cord hemicordectomy injury. This study (see Teng, Y. D., et al., 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,

Table of Contents

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 suggest that 24 hours after contusion injury was an appropriate time for device implantation based on both histological evaluation and ex vivo Magnetic Resonance Imaging ("MRI") techniques. Based on these results, we conducted larger rat contusion studies in our laboratory. We evaluated functional recovery with the 21 point Basso, Beattie, and Bresnahan ("BBB") locomotor rating scale to assess open field locomotion. In the first 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. Immunofluorescence labeling within the remodeled tissue identified high levels of laminin, an absence of GFAP-positive astrocytes, as well as beta-3 tubulin positive axons. This indicated that the bioresorbable polymer scaffold device supports tissue formation and remodeling favorable for axon regrowth. Following spinal contusion injury, myelin-producing nerve cells called Schwann cells arise from either injured nerve roots or endogenous sources within the central nervous system. The Schwann cells migrate into the injury region, promoting axonal growth and remyelinating segmentally demyelinated axons. In rats implanted with the bioresorbable polymer scaffold device, we observed that Schwann cell myelination was extensive within preserved penumbra white matter and also that Schwann cell myelination was detected within the remodeled tissue. 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 supportive to axon sprouting and spinal cord activity.

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 to evaluate the bioresorbable polymer scaffold device in a non human primate. Our first study in African green monkeys established that unilateral thoracic hemicordectomy SCI (a new model in this species) produced a consistent functional deficit, and we observed a consistently positive response to scaffold implantation (see Pritchard, et al., 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 (see Slotkin, J.R., Pritchard, et al., Biodegradable scaffolds promote tissue remodeling and functional improvement in non-human primates with acute spinal cord injury. Biomaterials, 123, pp. 63-76). 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 electromyography 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 hemicordectomy compared to non implant controls, and improved recovery of locomotion in subjects with full unilateral hemicordectomy lesions (see Slotkin, J.R., et al., Biodegradable scaffolds promote tissue remodeling and functional improvement in non-human primates with acute spinal cord injury, Biomaterials, 123, pg. 63-76, 2017).

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 a 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, the 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. 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 SCI. As part of our study, we placed bioresorbable polymer scaffold devices into the resulting contusion induced spinal cord cavity. 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, these non-clinical studies in two rat SCI models, the African green monkey unilateral hemicordectomy injury model, and the pig contusion injury model, demonstrate that the bioresorbable polymer scaffold

Table of Contents

device, surgically implanted at the epicenter of the wound after an acute SCI, acts by appositional healing to help spare spinal cord tissue, decrease post-traumatic cyst formation, decrease spinal cord tissue pressure, and promote tissue remodeling supportive to axon sprouting and spinal cord activity.

Completed Pilot Study

We conducted an early feasibility human pilot study, as the initial phase of a larger pivotal study, of our Neuro-Spinal Scaffold under our approved Investigational Device Exemption ("IDE") application for the treatment of complete, traumatic acute SCI. The study was intended to assess the safety and feasibility of the Neuro-Spinal Scaffold for the treatment of complete thoracic functional SCI, as well as to gather preliminary evidence of the clinical effectiveness of the Neuro-Spinal Scaffold.

The pilot study was initially approved for five subjects in up to six clinical sites across the United States, and was later modified to increase the number of allowable clinical sites to up to 20 and to permit enrollment of up to 10 subjects. The pilot study was initially staggered such that each patient that met the eligibility criteria would be followed for three months prior to enrolling the next patient in the study. In December 2014, the FDA approved an expedited enrollment plan that allowed us to continue enrolling patients more rapidly barring any significant safety issues. We enrolled five subjects in the pilot study between October 2014 and September 2015. The FDA approved conversion of this pilot study to a pivotal probable benefit study, [which we refer to as] The INSPIRE Study, that includes data from the patients enrolled in the pilot study.

The INSPIRE Study

Our Neuro-Spinal Scaffold implant is currently being studied in a pivotal probable benefit study formally known as The INSPIRE Study: InVivo Study of Probable Benefit of the Neuro-Spinal Scaffold for Safety and Neurologic Recovery in Subjects with Complete Thoracic AIS A Spinal Cord Injury. The FDA approved converting the pilot study into The INSPIRE Study in January 2016. The purpose of the study is to evaluate whether the Neuro-Spinal Scaffold implant is safe and demonstrates probable benefit for the treatment of complete T2-T12/L1 SCI. The primary endpoint is currently defined as the proportion of patients achieving an improvement of at least one AIS grade by six months' post- implantation. Additional endpoints include a reduction in pain and improvements in sensory and motor scores, bladder and bowel function, Spinal Cord Independence Measure, and quality of life.

After review of the six-month pilot study data package, the FDA approved The INSPIRE Study to expand enrollment from 12 to up to 30 patients. This allows us to account for events such as screen failures or deaths and still have 20 evaluable patients at the end of The INSPIRE Study. We may choose to enroll additional patients after 20 patients have received the Neuro-Spinal Scaffold implant to ensure that there are 20 evaluable patients with six months of follow-up data for the primary endpoint analysis. We are targeting completion of enrollment of the study as currently

designed in the third quarter of 2017, with submission of an HDE application in early 2018. As of March 1, 2017, there were 27 U.S. clinical sites and 3 Canadian clinical sites participating in The INSPIRE Study. We anticipate opening additional sites in the United States, Canada, and the United Kingdom.

In February 2016, we received approval of a protocol amendment for The INSPIRE Study. The amended protocol established an Objective Performance Criterion ("OPC"), which is a measure of study success used in clinical studies designed to demonstrate safety and probable benefit in support of an HDE approval. Although The INSPIRE Study is currently structured with the OPC as the primary component for demonstrating probable benefit, the OPC is not the only variable that the FDA would evaluate when reviewing a future HDE application. Approval is not guaranteed if the OPC is met, and even if the OPC is not met, the FDA may approve a medical device if probable benefit is supported by a comprehensive review of all clinical endpoints and preclinical results, as demonstrated by the sponsor's body of evidence. In May 2016, the FDA reintroduced the request that we include a randomized, concurrent control arm in the study as part of a study design consideration. As an alternative to a concurrent control, we plan to conduct a Contemporary Thoracic SCI Cohort Study (the "Cohort Study"). Utilizing existing databases and registries, we plan to develop a historical comparator that, to the extent possible, matches patients to those patients enrolled in The INSPIRE Study. Moreover, only patients injured since 2010 will be included as part of the Cohort Study, which provides a period that is nearly concurrent with The INSPIRE Study.

In late February 2016, the FDA accepted our proposed HDE modular shell submission and review process for the Neuro-Spinal Scaffold. The HDE modular shell is comprised of three modules: a preclinical studies module, a

Table of Contents

manufacturing module, and a clinical data module. As part of its review process, the FDA reviews modules, which are individual sections of the HDE submission, on a rolling basis. Following the submission of each module, the FDA reviews and provides feedback, typically within 90 days, allowing the applicant to receive feedback and potentially resolve any deficiencies during the review process. Upon receipt of the final module, which constitutes the complete HDE submission, the FDA will make a filing decision which may trigger the review clock for an approval decision.

As of March 1, 2017, 11 patients are in follow-up in The INSPIRE Study, and six of the patients have improved from complete AIS A SCI to incomplete SCI (one patient to AIS C and five patients to AIS B) by the six-month post-injury assessment. Two of the patients have not yet reached the six-month assessment point. There have been two patient deaths in The INSPIRE Study, neither of which was determined by the principal investigators and the Data and Safety Monitoring Board to be related to either the Neuro-Spinal Scaffold or the implant procedure. Results to date may not be indicative of results for the entire trial and marketing approval is not guaranteed even if the OPC is met. Results from patients enrolled to date may not be indicative of results for the entire trial and marketing approval is not guaranteed even if the OPC is met. For further information, see “Risk Factors - 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.”

Pilot Study in Acute, Cervical SCI

In addition to the thoracic pivotal study described above, we are in active discussions with Health Canada to initiate an early feasibility human pilot study, as the initial phase of a larger pivotal study, of our Neuro-Spinal Scaffold under an Investigational Testing Authorization application (“ITA”) for the treatment of complete, traumatic cervical acute SCI. We expect that the pilot study will be approved and initiated in the first half of 2017.

Although we desire to support a similar cervical study in the United States, the FDA has notified us that our proposed study was disapproved in the United States, pending submission of additional data from The INSPIRE Study. We remain in discussions with the FDA regarding such disapproval and are hopeful that data generated in The INSPIRE Study will support moving into cervical SCI in the United States.

Therapeutic Trails™ injection program for chronic SCI

In December 2015, we announced our preclinical Therapeutic Trails injection program for the treatment of chronic SCI. Therapeutic Trails are a local spinal cord delivery platform for proteins, genes, and cells. To support this program, we entered into an exclusive license agreement with the University of California, San Diego and an assignment agreement with James Guest, M.D., Ph.D., for issued patents covering technology related to the

Therapeutic Trails program, filed patent applications in the United States and internationally in support of the Therapeutic Trails injection program, and developed the TrailMakerTM injection device. We are exploring the utility of the TrailMaker injection device as a delivery platform supporting localized delivery of a variety of therapeutic agents including cells, proteins, and gene therapy vectors. We are targeting FDA interaction and guidance on localized delivery of therapeutics by the end of 2017. For further information on the regulatory pathway for the Therapeutic Trails injection product, please see “Government Regulation” below.

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 ScaffoldTM implant 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 eight

Table of Contents

issued United States patents and eight issued international patents expiring between 2018 and 2027, and one pending United States patent application and 11 pending international patent applications.

The BCH License has a term of 15 years, or as long as the life of the last expiring patent right under the license, 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 to 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 the development 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, whether generated by us or a sublicensee. We have the first right of negotiation with BCH and MIT 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 the 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 in the low single digits of net sales of any product that uses the licensed technology.

In addition to the rights we license under the BCH license, we have additional rights relating to the Neuro-Spinal Scaffold. Together with MIT, we co own patent application No. U.S. 14/232,525 (“Poly((lactic co glycolic acid) b lysine) and process for synthesizing a block copolymer of PLGA and PLL (poly e cbz l lysine)”). We also own patent application No. U.S. 13/793,231 (“Protective packaging with product preparation features incorporated”) and patent application No. U.S. 13/930,829 (“cupped forceps”).

To support our Therapeutic Trails program, we entered into agreements with the University of California, San Diego (“UC San Diego”) and James Guest, M.D., Ph.D., to expand our intellectual property portfolio. We entered into an

exclusive license agreement with UC San Diego (the "UC San Diego License") for an issued patent that expires in 2031. The UC San Diego License term runs as long as the life of the last expiring patent right under the license, unless terminated earlier by UC San Diego. We also entered into an assignment agreement with Dr. Guest for an issued patent that expires in 2024. We also have filed patent applications in the United States and internationally in support of the Therapeutic Trails injection program with the United States Patent and Trademark Office.

Government Regulation

The testing, manufacturing, and potential labeling, advertising, promotion, distribution, import, and marketing of our products are subject to extensive regulation by governmental authorities in the United States and in other countries. In the United States, the FDA, under the Public Health Service Act, the Federal Food, Drug and Cosmetic Act ("FDCA"), and their implementing regulations, regulates biologics and medical device products. In addition, our products under development are subject to extensive regulation by other U.S. federal and state regulatory bodies and comparable authorities in other countries. To ensure that medical products distributed domestically are safe and effective for their intended use, the FDA and comparable authorities in other countries have imposed regulations that govern, among other things, the following activities that we or our partners perform or will perform:

· product design and development;

Table of Contents

- product testing;
- product manufacturing;
- product labeling;
- product storage;
- premarket clearance, approval, or CE marking of products;
- advertising and promotion;
- product marketing, sales, and distribution; and
- post market surveillance reporting, including reporting of death or serious injuries.

The labeling, advertising, promotion, marketing, and distribution of biopharmaceuticals, or biologics, and medical devices also must be in compliance with the FDA requirements which include, among others, standards and regulations for off label promotion, industry sponsored scientific and educational activities, promotional activities involving the internet, and direct to consumer advertising. In addition, the Federal Trade Commission ("FTC") also regulates the advertising of many medical devices. The FDA and the FTC have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing us to correct deviations from regulatory standards and enforcement actions that can include seizures, injunctions, and criminal prosecution. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims.

The FDA has broad premarket, post-market, and regulatory enforcement powers. As with medical devices, manufacturers of biologics and combination products are subject to unannounced inspections by the FDA to determine compliance with applicable regulations, and these inspections may include the manufacturing facilities of some of our subcontractors. Failure by manufacturers or their suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities. Potential FDA enforcement actions include:

- warning letters, fines, injunctions, consent decrees, and civil penalties;

- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, or 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 on HDE or premarket approval applications ("PMA") of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances on HDE or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Table of Contents

FDA Regulation—Medical Device Products

FDA's Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either prior 510(k) clearance or prior premarket approval from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risk are placed in either Class I or II, which requires the manufacturer to submit to the FDA a premarket notification which must be cleared by the FDA before the medical device may be distributed commercially. This process is known as 510(k) clearance. Most Class I devices are exempt from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life sustaining, life supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III, requiring premarket approval or approval of an HDE. We expect the Neuro-Spinal Scaffold implant will be regulated by the FDA as a Class III medical device.

Premarket Approval Pathway

A PMA must be submitted if the device cannot be cleared through the 510(k) process. A PMA must be supported by extensive data including, but not limited to, technical, preclinical, and other non-clinical, clinical, and manufacturing and labeling information to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use.

If the FDA determines that a PMA submission is sufficiently complete, the FDA will accept the application for filing and begin an in depth review of the submitted information. By statute, the FDA has 180 days to review the "accepted application," although, generally, review of the application can take between one and three years, and it may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulations. New PMAs or PMA supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling, and design. Premarket approval supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA, and may not require as extensive clinical data or the convening of an advisory panel.

Humanitarian Device Exemption

Alternatively, a Class III device may qualify for FDA approval to be distributed under an HDE rather than a PMA. For a device to be eligible for an HDE, it must be first designated by the FDA as an HUD intended to benefit patients in the treatment or diagnosis of a disease or condition that affects fewer than 8,000 individuals in the United States per year (increased by the 21st Century Cures Act from 4,000 to 8,000). The HDE pathway also requires that 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 and, although exempt from the effectiveness requirements of a PMA, an HDE does require sufficient information for the 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. In addition, an HUD may only be used in facilities that have established a local institutional review board ("IRB") to supervise clinical testing of devices, and after an IRB has approved the use of the device to treat or diagnose the specific disease.

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. We expect our Neuro-Spinal Scaffold may meet the eligibility criteria to be sold for a profit.

Table of Contents

Clinical Trials

Clinical trials are almost always required to support a PMA or HDE application. If the device presents a “significant risk” to human health as defined by the FDA, the FDA requires the device sponsor to submit an IDE to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a “non-significant risk” device, in which case an IDE approval from the FDA would not be required, although the clinical trial would need to meet other requirements including IRB approval. Clinical trials for a significant risk device may begin once an IDE is approved by the FDA and the appropriate IRB at each clinical trial site. Future clinical trials may require that we obtain an IDE from the FDA prior to commencing any such clinical trial and that the trial be conducted with the oversight of an IRB at the clinical trial site.

Our clinical trials must be conducted in accordance with FDA regulations and federal and state regulations concerning human subject protection, including informed consent and healthcare privacy. A clinical trial may be suspended by the FDA or at a specific site by the relevant IRB at any time for various reasons, including a belief that the risks to the trial participants outweigh the benefits of participation in the clinical trial. Even if a clinical trial is completed, the results of our clinical testing may not demonstrate the safety and efficacy of the device, or may be equivocal or otherwise not be sufficient for us to obtain approval of our product.

Pervasive and Continuing FDA Regulation

After a device is placed on the market, numerous regulatory requirements continue to apply. These include:

· product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;

· Quality System Regulation (“QSR”), which requires manufacturers, including third party manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the manufacturing process;

· labeling regulations and FDA prohibitions against the promotion of products for uncleared or unapproved indications or other off label uses;

.

clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;

- approval of product modifications that affect the safety or effectiveness of one of our approved devices;

- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;

- post approval restrictions or conditions, including post approval study commitments;

- post market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;

- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;

- regulations pertaining to voluntary recalls; and

- notices of corrections or removals.

Table of Contents

We and any third party manufacturers that we use must register with the FDA as medical device manufacturers and must obtain all necessary state permits or licenses to operate our business. As manufacturers, we and any third party manufacturers that we use are subject to announced and unannounced inspections by the FDA to determine our compliance with quality system regulation and other regulations. We have not yet been inspected by the FDA. We believe that we are in substantial compliance with quality system regulation and other regulations.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees, and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, or 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 on HDE or PMA of new products or modified products;
- operating restrictions;
- withdrawing 510(k) clearances on HDE or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Regulatory Pathway for the Neuro-Spinal ScaffoldTM Implant

We expect the Neuro-Spinal Scaffold will be regulated by the FDA as a Class III medical device. The FDA granted HUD designation for our Neuro-Spinal Scaffold implant in 2013 for use in complete SCI (defined as less than 4,000

patients per year), thus allowing us to potentially qualify for FDA approval under an HDE. In 2015, we received conditional approval from the FDA to convert our ongoing pilot study into a pivotal probable benefit study. Full approval of such conversion was subsequently granted in January 2016. We are currently in discussion with the FDA regarding the clinical data package that would support future HDE approval for the 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 implant or any future devices or modifications to Neuro-Spinal Scaffold implant or such devices for which we may submit a PMA or HDE application.

European Economic Area (the “EEA”)

Sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. In order to market our products outside the United States, we must obtain regulatory approvals or CE Certificates of Conformity and comply with extensive safety and quality regulations. The time required to obtain approval by a foreign country or to obtain a CE Certificate of Conformity may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ. In the EEA, we are required to obtain Certificates of

Table of Contents

Conformity before drawing up a European Commission ("EC") Declaration of Conformity and affixing the CE mark to our medical devices. Many other countries, such as Australia, India, New Zealand, Pakistan and Sri Lanka, accept CE Certificates of Conformity or FDA clearance or approval although others, such as Brazil, Canada and Japan, require separate regulatory filings.

In the EEA, our devices are required to comply with the Essential Requirements laid down in Annex I to the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, known as the Medical Devices Directive ("MDD"). Compliance with these requirements entitles us to affix the CE mark to our medical devices, without which they cannot be commercialized in the EEA. To demonstrate compliance with the Essential Requirements laid down in Annex I to the MDD and obtain the right to affix the CE mark to our medical devices, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I with no measuring function and which are not sterile), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements laid down in the Medical Devices Directive, a conformity assessment procedure requires the intervention of a "Notified Body", which is an organization designated by the competent authorities of an EEA country to conduct conformity assessments. The Notified Body would typically audit and examine a product's Technical File or Design Dossier and the quality system for the manufacture, design, and final inspection of a device before issuing a CE Certificate of Conformity demonstrating compliance with the relevant Essential Requirements laid down in Annex I to the Medical Devices Directive. Following the issuance of a CE Certificate of Conformity, we could draw up an EC Declaration of Conformity and affix the CE mark to the products covered by such CE Certificate of Conformity and the EC Declaration of Conformity. We have not yet applied for a CE Mark for the Neuro-Spinal Scaffold.

On September 26, 2012, the European Commission adopted a package of legislative proposals designed to replace the existing regulatory framework for medical devices in the European Union. These proposals are intended to strengthen the medical devices rules in the European Union. On February 22, 2017, after finalization of a final linguistic review of the texts and the last revisions, the final text of the MDR and IVDR were published on the Council of the European Union's website. The regulations are now anticipated to be definitively adopted by the Council and the European Parliament by the end of the March 2017. The regulations, which will substantially impact medical devices manufacturers, will be applicable from May 2020 for the MDR and May 2022 for the IVDR. Examples of the changes which will be introduced by the regulations include the following:

- Additional scrutiny during the conformity assessment procedure for high risk medical devices;

- Strengthening of the clinical data requirements related to medical devices;

- Strengthening of the designation and monitoring processes governing notified bodies;

- The obligation for manufacturers and authorized representatives to have a person responsible for regulatory compliance continuously at their disposal;

- Authorized representatives would be held legally responsible and liable for defective products placed on the EU market;

- Increased traceability of medical devices following the introduction of a Unique Device Identification ("UDI") system;

- New rules governing the reprocessing of medical devices;

- Increased transparency with the establishment of EUDAMED III as information from several databases concerning economic operators, CE Certificates of Conformity, conformity assessment, clinical investigations, the UDI system, adverse event reporting, and market surveillance would be available to the public.

After a product has been CE marked and placed on the market in the EEA, we would need to comply with a number of regulatory requirements relating to:

- registration/notification of medical devices in individual EEA countries;

Table of Contents

- pricing and reimbursement of medical devices;

- establishment of post marketing surveillance and adverse event reporting procedures;

- Field Safety Corrective Actions, including product recalls and withdrawals;

- marketing and promotion of medical devices; and

- interactions with physicians.

Failure to comply with these requirements at such time could result in enforcement measures being taken against us by the competent authorities of the EEA countries. These can include fines, administrative penalties, compulsory product withdraws, injunctions, and criminal prosecution. Such enforcement measures would have an adverse effect on our capacity to market our products in the EEA and, consequently, on our business and financial position. Such failures could also lead to cancelation, suspension, or variation of our CE Certificates of Conformity by the relevant Notified Body.

Further, the advertising and promotion of our products in the EEA is subject to the provisions of the Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other national legislation in the individual EEA countries governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

FDA Regulation - Combination Products/Biologics

We believe that our Therapeutic Trails injection investigational product under development will be defined as a combination product consisting of two or more regulated components, that is, a medical device in combination with either a drug or biological drug. In the United States, these various components, when standalone, would be regulated by different centers. Specifically, the drug or biological drug component of a therapeutic product could, depending on the nature of the product, be regulated by the FDA as either a conventional drug under either a new drug application (“NDA”) or as a biological drug under a biologics license application (“BLA”). The FDA’s Center for Drug Evaluation and Research (“CDER”) has primary regulatory oversight of drug products. In order to be marketed, most new prescription drugs must be approved under an NDA in accordance with the FDCA. By contrast, biological drugs can be regulated either by CDER or a combination product is assigned by the FDA to one of the agency’s centers, such as the Center for Biologics Evaluation and Research (“CBER”) and, in order to be marketed, must be approved under a BLA in

accordance with the Public Health Service Act ("PHSA"). Although requirements for NDAs and BLAs are similar, each has certain requirements that are unique to themselves. In addition, when these drugs or biological drugs are combined with a device in a "combination product", the resulting product is assigned by the FDA to one center (CDER, CBER or the Center for Devices and Radiological Health ("CDRH")) depending on the regulatory assignment of the components and the primary mechanism of action. For example, if the combination product contains a biological drug and the primary mode of action of the product is determined to be chemical or metabolic, then the entire combination product would likely be assigned to CBER for regulation under the BLA process with consulting input by CDRH.

Therapeutic products such as our Therapeutic Trails could be regulated as a combination product which involves an initial assignment by the FDA to one of the agency's centers, such as the CDER, CBER, or CDRH, with the chosen center to take the lead in premarketing review and approval of the combination product. Other FDA centers also may review the product in regard to matters that are within their expertise. The FDA selects the lead center based on an assessment of the combination product's "primary mode of action." Some products also may require approval or clearance from more than one FDA center.

To determine which FDA center or centers will review a combination product submission, companies may submit a request for assignment to the FDA. Those requests may be handled formally or informally. In some cases, jurisdiction may be determined informally based on FDA experience with similar products. However, informal jurisdictional determinations are not binding on the FDA. Companies also may submit a formal Request for Designation to the FDA Office of Combination Products. The Office of Combination Products will review the request and make its

Table of Contents

jurisdictional determination within 60 days of receiving a Request for Designation. Stem cell based therapies and gene therapy vectors are typically regulated under the jurisdiction of the CBER, and require the submission of an Investigational New Drug application ("IND") to the FDA before clinical studies of the product may proceed; additionally, these products generally require submission of a BLA for marketing approval. Most therapeutic proteins are regulated under the jurisdiction of CDER, and require an IND before clinical studies may proceed, and the submission of an NDA for marketing approval.

The IND and BLA or NDA Approval Process

As summarized above, drugs and biological drugs must satisfy the requirements of either the FDCA or the PHSA and their implementing regulations. Additionally, most prescription drugs and biological drugs must be approved under an NDA or BLA before they can be marketed in the United States.

Both NDAs and BLAs require extensive studies and submission of a large amount of data by the applicant. The steps for obtaining FDA approval of an NDA or BLA in the United States include the following:

Preclinical Testing. Before testing any compound in human subjects in the United States, a company must generate extensive preclinical data. Preclinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the quality and safety of the product. Animal studies must be performed in compliance with the FDA's Good Laboratory Practice ("GLP") regulations and the United States Department of Agriculture's Animal Welfare Act.

IND Submission. Human clinical trials in the United States cannot commence until an IND is submitted and becomes effective. A company must submit preclinical testing results to the FDA as part of the IND, and the FDA must evaluate whether there is an adequate basis for testing the drug in initial clinical studies in human volunteers. Unless the FDA raises concerns, the IND becomes effective 30 days following its receipt by the FDA. Once human clinical trials have commenced, the FDA may stop the clinical trials by placing them on "clinical hold" because of concerns about the safety of the product being tested, or for other reasons.

Clinical Trials. Clinical trials involve the administration of the drug to healthy human volunteers or to patients, under the supervision of a qualified investigator. The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA's bioresearch monitoring, recordkeeping regulations, and Good Clinical Practice ("GCP") requirements, which establish standards for conducting, recording data from, and reporting requirements for the results of clinical trials and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. Clinical trials must be conducted under the oversight of an IRB for the relevant clinical protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. Each protocol is reviewed by the FDA as part of the IND. In

addition, each clinical trial site must be reviewed and approved by, and conducted under, the auspices of an IRB. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with FDA requirements, including but not limited to those relating to GCP clinical, as applicable, regulations and guidelines for obtaining informed consent from the study subjects, following the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of adverse events. Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the United States. Data from a foreign study not conducted under an IND may be submitted in support of an NDA or BLA if the study was conducted in accordance with GCP and the FDA is able to validate the data.

Clinical trials involving drugs and biologics are typically conducted in three sequential phases, which may overlap or be combined. These phases are described generally below.

· Phase I. Phase I clinical trials involve the initial introduction of the investigational drug or biologic into healthy human subjects to test for safety, dosage tolerance, absorption, metabolism, distribution, and excretion. This testing is also generally intended to determine the side effects associated with increasing doses and, if possible, to gain early evidence of effectiveness. In the case of some products for severe or life threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with the targeted disease or disorder.

Table of Contents

- Phase II. Phase II clinical trials usually involve studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific, targeted indications, to determine dosage tolerance and optimal dosage, and to identify possible adverse effects and safety risks.

- Phase III. Phase III clinical trials involve studies undertaken to further evaluate dosage, clinical efficacy, and safety in an expanded patient population at geographically dispersed clinical sites. These studies are intended to evaluate the overall risk benefit profile of the product by obtaining statistical evidence of safety and effectiveness at the proposed dosing regimen for drugs, or the safety, purity, and potency of a biological product. These studies also aim to provide an adequate basis for product labeling.

Clinical testing may not be completed successfully within any specified time period, if at all, and may not generate conclusive or statistically meaningful data. The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted under an IND and may, at its discretion, reevaluate, alter, suspend, or terminate the testing based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to the patient. The FDA, IRB, or the sponsor may suspend or terminate clinical trials at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The FDA can also request that additional preclinical studies or clinical trials be conducted as a condition to product approval. Additionally, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

BLA/NDA Submission and Review. After completing clinical testing of an investigational drug or biologic, a sponsor must prepare and submit a BLA or NDA for review and approval by the FDA. The BLA or NDA is a comprehensive, multi-volume application that includes, among other things, the results of preclinical and clinical studies, and of the clinical trials, information about the drug's composition, and plans for manufacturing, packaging, and labeling the drug. In most cases, the BLA or NDA must be accompanied by a substantial user fee. The FDA will initially review the BLA or NDA for completeness before it accepts the BLA or NDA for filing. There can be no assurance that the submission will be accepted for filing or that the FDA may not issue a refusal to file ("RTF"). If an RTF is issued, there is opportunity for dialogue between the sponsor and the FDA in an effort to resolve all concerns. If the BLA or NDA submission is accepted for filing, the FDA will begin an in depth review of the BLA or NDA to determine, among other things, whether a product is safe and effective for its intended use and whether the product is being manufactured in accordance with current Good Manufacturing Practices ("cGMP") to assure and preserve the product's identity, strength, quality, and purity. If the biological product or drug contains a new active ingredient not previously approved, the BLA or NDA automatically will be referred to an appropriate advisory committee for review prior to approval of the biological product or drug, unless the FDA decides otherwise and specifies such reasons in a complete response letter to the sponsor. The FDA, however, is not bound by the opinion of the advisory committee.

Companies also may seek fast track designation for their products. Fast track products are those that are intended for the treatment of a serious or life threatening condition and that demonstrate the potential to address unmet medical needs for such a condition. If awarded, the fast track designation applies to the product only for the indication for which the designation was received. Fast track products are eligible for two means of potentially expediting product development and FDA review of BLAs or NDAs. First, a fast track product may be approved on the basis of either a clinical endpoint or a surrogate endpoint that is reasonably likely to predict clinical benefit. Approvals of this kind may be subject to requirements for appropriate post approval studies to validate the surrogate endpoint or otherwise

confirm the effect on the clinical endpoint, and to certain other conditions. Second, if the FDA determines after review of preliminary clinical data submitted by the sponsor that a fast track product may be effective, it may begin review of portions of a BLA or NDA before the sponsor submits the complete BLA or NDA, thereby accelerating the date on which review of a portion of the BLA or NDA can begin. There can be no assurance that any of our other products will receive designation as fast track products. Even if they are designated as fast track products, we cannot assure you that our products will be reviewed or approved more expeditiously for their fast track indications than would otherwise have been the case, or that such products will be approved promptly, or at all. Furthermore, the FDA can revoke previously granted fast track status at any time.

In addition, products studied for their safety and effectiveness in treating serious or life threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well controlled clinical trials establishing that the therapeutic product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical

Table of Contents

endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a product receiving accelerated approval perform adequate and well controlled post approval clinical trials to verify and further define the product's clinical benefit and safety profile. There can be no assurance that any of our products will receive accelerated approval. Even if accelerated approval is granted, the FDA may withdraw such approval if the sponsor fails to conduct the required post approval clinical trials, or if the post approval clinical trials fail to confirm the early benefits seen during the accelerated approval process.

Fast track designation and accelerated approval should be distinguished from priority review although products awarded fast track status may also be eligible for priority review. Products regulated by the CBER or CDER may receive priority review if they provide significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious or life threatening disease. Products awarded priority review are given abbreviated review goals by the agency. The FDA has agreed to a performance goal of reviewing products awarded priority review within six months, whereas products under standard review receive a ten month target. The review process, however, is often significantly extended by FDA requests for additional information or clarification regarding information already provided in the submission. Priority review is requested at the time a BLA or NDA is submitted, and the FDA makes a decision as part of the agency's review of the application for filing.

If granted, fast track designation, accelerated approval, and priority review may expedite the approval process, but they do not change the standards for approval.

The testing and approval processes require substantial time, effort, and financial resources, and each may take several years to complete. Data obtained from clinical activities are not always conclusive, which could delay, limit, or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. The FDA may decide to not approve the application or issue a Complete Response letter outlining the deficiencies in the submission. The Complete Response letter also may request additional information, including additional preclinical or clinical data. Even if such additional information and data are submitted, the FDA may decide that the NDA still does not meet the standards for approval. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. The FDA may limit the indications for use or place other conditions, such as post-approval studies, on any approvals that could restrict the commercial application of the products. Post-approval studies, often referred to as "Phase IV" or "post-marketing" studies, may be subject to completion deadlines. The FDA may also determine that a Risk Evaluation and Mitigation Strategy ("REMS") is necessary to ensure that the benefits of a new product outweigh its risks, and the product can therefore be approved. A REMS may include various elements, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug. Under the Pediatric Research Equity Act, certain applications for approval must include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject drug or biological product in relevant pediatric populations.

After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and further submission of a new or supplemental BLA or NDA for FDA review and approval.

Post Approval Requirements

After regulatory approval of a product is obtained, companies are required to comply with a number of post approval requirements, including cGMP requirements, relating to manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, distribution, and recordkeeping. For example, as a condition of approval of a BLA or NDA, the FDA may require post approval testing and surveillance to monitor the product's safety or efficacy. In addition, holders of an approved BLA or NDA are required to keep extensive records, to report certain adverse reactions and production deviations and problems to the FDA, to provide updated safety and efficacy information, and to comply with requirements concerning advertising and promotional labeling for their products. If, after receiving approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the BLA or NDA), additional regulatory review and approval may be required. The FDA also conducts regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval of a product. If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities, or previously unknown problems with any approved commercial products, manufacturers, or manufacturing processes are discovered, we could be subject to administrative or judicially imposed

Table of Contents

sanctions, including fines, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Post Approval (Phase IV). Post approval clinical trials are required of, or agreed to by, a sponsor as a condition of, or subsequent to, marketing approval. Further, if the FDA becomes aware of new safety information about an approved product, it is authorized to require post approval trials of the biological product. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. Failure to promptly conduct Phase IV clinical trials could result in withdrawal of approval for products approved under accelerated approval regulations.

Regulatory Pathway for Therapeutic Trails

Our Therapeutic Trails injection investigational product is expected to be regulated as a combination product. Combination products are therapeutic and diagnostic products that combine drugs, devices, and/or biological drug products. As described above, a combination product is assigned to an FDA center based on a determination of the "primary mode of action" of the combination product. We are exploring the utility of the TrailMakerTM injection device as a delivery platform supporting localized delivery of a variety of therapeutic agents including cells, proteins, and gene therapy vectors. Stem cell based therapies and gene therapy vectors are regulated under the jurisdiction of the CBER, typically requiring an IND and a BLA for marketing approval. The formal jurisdiction assignment process is achieved through the request for designation process. Therapeutic proteins are generally regulated under the jurisdiction of CDER, and typically require an IND and an NDA for marketing approval. We are targeting FDA interaction and guidance on localized delivery of therapeutics by the end of 2017.

Financial Information and Research and Development Expenditures

We have incurred net losses each year since our inception, including net losses of $23.4 million for the year ended December 31, 2016, $33.3 million for the year ended December 31, 2015, and $18.3 million for the year ended December 31, 2014. 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 have devoted most of our financial resources to research and development, including our clinical and preclinical development activities related to our Neuro Spinal Scaffold implant. Our research and development expenditures, which include research and development related to our product candidates, were $12.6 million, $10.1 million and $10.3 million in 2016, 2015, and 2014, 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.

Table of Contents

Manufacturing

We have developed a proprietary manufacturing process to build our Neuro-Spinal ScaffoldTM implant. We manufacture our implants 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 10-K) 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 vendors for our critical raw materials; however, these materials are also available from other vendors. We are currently manufacturing our Neuro-Spinal Scaffold implant to support The INSPIRE Study and a cervical SCI Study. As we move toward preparing for commercialization, we intend to be compliant with all applicable regulations on a country specific basis.

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 we may sell direct or through distributors in major 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 neurosurgeons, orthopedic spine surgeons, and trauma surgeons, and would expect to provide a high level of service for any of our approved 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 the 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.

Segment and Geographic 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, we have viewed our operations and managed our business as principally one operating segment, which is developing and commercializing biopolymer scaffolding devices for the treatment of SCIs. As of December 31, 2016, 2015, and 2014, all of our assets were located in one location in the United States.

Employees

As of December 31, 2016, we had 37 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 acquisition.

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

Table of Contents

accessible through, our website is not a part of, and is not incorporated by reference into, this Annual Report on Form 10-K.

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.

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

Information appearing on the above websites is not a part of, and is not incorporated in, this Annual Report on Form 10-K. Further, our references to the URLs for these websites are intended to be inactive textual reference only.

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 Financial Position and Need for Additional Capital

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 $23.4 million for the year ended December 31, 2016 and $33.3 million for the year ended December 31, 2015. As of December 31, 2016, we had an accumulated deficit of $157.0 million. We have a limited operating history on which to base an evaluation of our business and investors should consider the risks and difficulties frequently encountered by early-stage companies in new and rapidly evolving markets, particularly companies engaged in the development of medical devices. 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. Moreover, we may allocate significant amounts of capital towards products and technologies for which market demand is lower than anticipated and, as a result, may not achieve expectations or may elect to abandon such efforts.

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 implant. 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, the Neuro-Spinal Scaffold implant, is currently being studied in a pivotal probable benefit study and, as a result, we expect that it could 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 implant 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 payers, and other factors.

Table of Contents

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 pivotal probable benefit study of our Neuro-Spinal Scaffold implant;
- 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.

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

Our financial statements as of December 31, 2016 were prepared under the assumption that we will continue as a going concern. At December 31, 2016, we had cash, cash equivalents, and marketable securities of $33.0 million. Given our development plans, we estimate cash resources will be sufficient to fund our operations into the beginning of the second quarter of 2018. This estimate is based on assumptions that may prove to be wrong; expenses could prove to be significantly higher, leading to a more rapid consumption of our existing resources.

Our ability to continue as a going concern depends on our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all. Based on these factors, management determined that there is substantial doubt regarding our ability to continue as a going concern. Our independent registered public accounting firm has expressed substantial doubt as to our ability to continue as a going concern in its report dated March 10, 2017 included elsewhere in this Form 10-K.

Table of Contents

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 pivotal probable benefit study of, and seek regulatory approval for, our Neuro-Spinal Scaffold implant. 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, 2016, our consolidated cash, cash equivalents, and marketable securities balance was approximately $33.0. We believe our current cash, cash equivalents, and marketable securities are adequate to fund our operations into the beginning of the second quarter of 2018. However, since it is only an estimate and based on a number of factors, we may consume our resources earlier than anticipated. Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern in its report on our financial statements. 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 implant and any other product candidates that we may develop or acquire;

- future clinical trial results of our Neuro-Spinal Scaffold implant;

- the timing of, and the costs involved in, obtaining regulatory approvals for the Neuro-Spinal Scaffold implant if our pivotal probable benefit study is successful, and the outcome of regulatory review of the Neuro-Spinal Scaffold implant;

- 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

Table of Contents

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, and if we are not successful in raising additional capital, we may not be able to continue as a going concern.

Raising additional capital may cause dilution to our existing 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 implant or any other product candidates that we develop or acquire.

Our ability to use our net operating loss carryforwards and tax credit carryforwards may be limited.

We have generated significant net operating loss carryforwards (“NOLs”) and research and development tax credits (“R&D credits”) as a result of our incurrence of losses and our conduct of research activities since inception. We generally are able to carry NOLs and R&D credits forward to reduce our tax liability in future years. However, our ability to utilize the NOLs and R&D credits is subject to the rules of Sections 382 and 383 of the Internal Revenue Code of 1986 (“the Code”), as amended, respectively. Those sections generally restrict the use of NOLs and R&D credits after an “ownership change.” An ownership change occurs if, among other things, the stockholders (or specified groups of stockholders) who own or have owned, directly or indirectly, 5% or more of a corporation’s common stock or are otherwise treated as 5% stockholders under Section 382 of the Code and the United States Treasury Department regulations promulgated thereunder increase their aggregate percentage ownership of that corporation’s stock by more than 50 percentage points over the lowest percentage of the stock owned by these stockholders over the applicable testing period. In the event of an ownership change, Section 382 imposes an annual limitation on the amount of taxable income a corporation may offset with NOL carryforwards and Section 383 imposes an annual limitation on the amount of tax a corporation may offset with business credit (including the R&D credit) carryforwards. Any unused annual limitation may be carried over to later years until the applicable expiration date for the respective NOL or R&D credit carryforwards. We have completed several financings since our inception, which may have resulted in a change in control as defined by Sections 382 and 383 of the Code, or could result in a change in control in the future, but we have not completed an analysis of whether a limitation as noted above exists. We have not performed a Section

382 study yet but we will complete an appropriate analysis before our tax attributes are utilized.

Table of Contents

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 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 operations 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 operations of the acquired business, or due to amortization or impairment costs for acquired goodwill and other intangible assets.

Risks Related to the Development, Regulatory Approval, and Commercialization of Our Product Candidates

We depend heavily on the success of one product candidate, the Neuro-Spinal ScaffoldTM implant, which is currently being studied in a pivotal probable benefit 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 implant.

We currently have only one product candidate, the Neuro-Spinal Scaffold implant, 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 implant, which is currently being studied in an ongoing pivotal probable benefit study, will require substantial additional clinical development, testing, manufacturing process development, and regulatory approval before we are permitted to commence its commercialization. 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 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 implant or any other product candidate.

Our other product candidate, Therapeutic Trails™, 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.

We may experience delays in our ongoing pivotal probable benefit study for our Neuro-Spinal Scaffold implant, and we do not know whether modifications to The INSPIRE Study will be necessary, including whether, future clinical trials will need to be conducted and/or whether The INSPIRE Study will need to be redesigned. Further, we do not know whether The INSPIRE Study and patient enrollment will be completed on schedule, if at all. Clinical studies for other future product candidates, including those above, may experience delays or may not begin.

Before we can obtain regulatory approval for the sale of our Neuro-Spinal Scaffold implant, we must complete the pivotal probable benefit study. Our Neuro-Spinal Scaffold implant is currently being studied in a 20-subject pivotal study under our approved IDE application for the treatment of complete thoracic traumatic acute spinal cord injury. Even

Table of Contents

though the initial results of our clinical studies in humans are promising, our results may subsequently fail to meet the safety and probable benefit standards required to obtain regulatory approvals. Our pivotal probable benefit 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 probable benefit of our Neuro-Spinal Scaffold implant, lack of adequate funding to continue the clinical trial, or unforeseen safety issues. In addition, we are currently in active discussions with the FDA regarding the set of clinical data that would support a future approval of the product. Modifications to our ongoing study due to those discussions may further delay completion of the study.

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

- obtain regulatory approval to commence future clinical trials;

- reach agreement on acceptable terms with prospective contract research organizations ("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 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 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 enroll 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, injury, 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;

Table of Contents

- 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.

For a period in 2016, as a result of an FDA pre-specified enrollment hold, we were unable to enroll patients in The INSPIRE Study pending FDA authorization to proceed with additional enrollment, which delayed our ability to open new sites and enroll patients at the pace we had anticipated. 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 our HDE which requires us to show the device does not 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. 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.

We are currently pursuing an HDE regulatory pathway in the United States for our Neuro-Spinal Scaffold. The HDE requires that there must be no other comparable device available to provide therapy for this condition and requires sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of

Table of Contents

illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use. The amended protocol for The INSPIRE Study, which was approved in February 2016, established an Objective Performance Criterion ("OPC"), which is a measure of study success used in clinical studies designed to demonstrate safety and probable benefit in support of an HDE approval. The OPC for The INSPIRE Study is currently defined as 25% or more of the patients in the study demonstrating an improvement of at least one AIS grade by six months post implantation. We are currently in discussions with the FDA regarding its request for changes to our pivotal probable benefit trial. We believe that the current study design is sufficient to demonstrate safety and probable benefit in support of an HDE application for marketing approval and we plan to provide to the FDA data from patient registries (the Cohort Study) that we believe will provide sufficient information for the 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. However, we cannot be certain whether the FDA will approve our HDE without additional information or studies. For example, the FDA has recommended that we include a randomized, concurrent control arm in the study as part of a study design consideration. In addition, although the study is currently structured with the OPC as the primary component for demonstrating probable benefit, the OPC is not the only variable that the FDA would evaluate when reviewing a future HDE application and there can be no assurance that the FDA will accept the OPC as sufficient for demonstrating probable benefit. Moreover, analysis of data from the patient registries may suggest amendments to the protocol for The INSPIRE Study, including adjustment to the existing OPC, which might create a higher threshold for evidencing probable benefit. In the event our assessment that the current study design, or any amended study design we propose based upon patient registries, is not acceptable to the FDA, the ability to obtain approval under the HDE pathway may be delayed or may not be feasible. If the FDA does not approve or clear our products in a timely fashion, or at all, our business and financial condition will be adversely affected.

The 21st Century Cures Act recently increased the upper population limit for an HDE from 4,000 to 8,000, which allows us to potentially request an expansion of our current HUD to include additional patient populations beyond our current HUD for complete SCI. If we choose to pursue such an expansion, this may cause our application to be delayed or cause the FDA to request additional information. In addition, our current study is not designed to support approval beyond complete SCI. Thus, expansion would require additional studies. We cannot be certain that we will be able to increase the potential population that we might be able to treat based on the HDE pathway. If any of these events occur, our business and financial condition 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 if the FDA subsequently approves another device for the same intended use, as well as limitations on the ability to profit from sales of the product.

If the FDA subsequently approves a PMA or clears a 510(k) for the HUD or another comparable device with the same indication, the FDA may withdraw the HDE. Once a comparable device becomes legally marketed through PMA approval or 510(k) clearance to treat or diagnose the disease or condition in question, there may no longer be a need for the HUD and so the HUD may no longer meet the requirements of section 520(m)(2)(B) of the FDCA.

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, under section 520(m)(6)(A)(i) of the FDCA, as amended by the Food and Drug Administration Safety and Innovation Act, an HUD 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. The legislation related to HUD/HDE profit eligibility expires on October 1, 2017 and may or may not be renewed.

Some of our future products will be viewed by the FDA as combination products comprised of a biologic and medical device component, and the review of combination products is often more complex and more time consuming than the review of other types of products.

It is possible that some of our products, including our Therapeutic Trails injection, may be regulated by the FDA as combination products. As explained above in the Government Regulation section, for a combination product, the

Table of Contents

FDA must determine which center or centers within the FDA will review the product candidate and under what legal authority the product candidate will be reviewed. We are currently developing our regulatory strategies with respect to which regulatory pathway will be necessary to obtain clearance or approval, if medical device clearance or approval is required at all. We believe that the biologic component of the Therapeutic Trails injection will be reviewed by the CBER, although it is possible that it will be regulated by the FDA's CDER. The delivery tools associated with that product may be reviewed by the CDRH, either separately as a medical device, or in consultation with CBER or CDER as part of the BLA or NDA. The process of obtaining FDA marketing clearance or approval is lengthy, expensive, and uncertain, and we cannot be sure that our biologic device combination products, or any other products, will be cleared or approved in a timely fashion, or at all. In addition, the review of combination products is often more complex and more time consuming than the review of a product candidate under the jurisdiction of only one center within the FDA. We cannot be sure that the FDA will not select to have our combination products reviewed and regulated by only one FDA center and/or different legal authority, in which case the path to regulatory approval would be different and could be more lengthy and costly. If the FDA does not approve or clear our products in a timely fashion, or at all, our business and financial condition will be adversely affected.

We may 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.

The results of our clinical trials may not support our product candidate claims or may result in the discovery of adverse side effects.

Our ongoing research and development, preclinical testing, and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. We are currently conducting a pivotal study of our Neuro-Spinal Scaffold implant to gather information about the product's safety and probable benefit. In the future, we may conduct clinical trials to support approval of new products. Clinical studies must be conducted in compliance with FDA regulations or the FDA may take enforcement action. The data collected from these clinical studies may ultimately be used to support market clearance for these products. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidate claims or that the FDA will agree with our conclusions regarding them. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and preclinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. 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.

Table of Contents

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 payers such as health insurance companies, and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. Physicians and hospitals will need to establish training and procedures to utilize and implement our Neuro-Spinal Scaffold implant, 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. Payers may view new products or products that have only recently been launched or with limited clinical data available, as investigational, unproven, or experimental, and on that basis may deny coverage of procedures involving use of our products. If our product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business.

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 regulatory 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 and results of operations.

In addition, we and our suppliers are required to comply with Good Manufacturing Practices ("GMPs") and Good Tissue Practices ("GTPs") with respect to any human cells and biologic products we may develop, and International Standards Organization ("ISO") regulations for the manufacture of our products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, and shipping of any product for which we obtain clearance or approval. Manufacturing may also be subject to controls by the FDA for parts of the combination products that the FDA may find are controlled by the biologics regulations.

The FDA audits compliance with the QSR and other similar regulatory requirements 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 premarket approval of new products or modified products;
- withdrawing PMA approvals that have already been granted;
- refusal to grant export approval for our products; or

Table of Contents

- criminal prosecution.

Any of these sanctions could have a material adverse effect on our reputation, business, results of operations, and financial condition.

Our 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 and biologic products and operations are subject to extensive regulation by the FDA and various other federal, state, and foreign governmental authorities. For example, we expect to initiate a clinical trial in Canada and will be subject to applicable Canadian regulations as we initiate and conduct that trial. Government regulation of medical devices and biologic products is meant to assure their safety and effectiveness, and includes regulation of, among other things:

- 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 medical device product in the United States, we must obtain clearance under Section 510(k) of the FDCA, approval of a PMA, or approval of an HDE, unless the device is specifically exempt from premarket review. Our Neuro-Spinal Scaffold implant is expected to be regulated by the FDA as a Class III medical device, requiring either PMA or HDE approval. An HUD designation was granted for the Neuro-Spinal Scaffold implant 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, preclinical, clinical trial, manufacturing, and labeling data. Modifications to products that are approved through a PMA 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.

Table of Contents

An HDE application is similar in form and content to a PMA and, although exempt from the effectiveness requirements of a PMA, an HDE does require sufficient information for the 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. Like a PMA, changes to HDE devices generally need FDA approval.

Biological products must satisfy the requirements of the Public Health Services Act and its implementing regulations. In order for a biologic product to be legally marketed in the U.S., the product must have a BLA approved by the FDA. The testing and approval process requires substantial time, effort, and financial resources, and each may take several years to complete.

The FDA can delay, limit, or deny clearance or approval of a product 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 preclinical 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.

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 post-marketing 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 regulators 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.

Table of Contents

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 our medical device products, or malfunction of our medical device products, cause or contribute to a death or a serious injury before or after approval, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers with approved products are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. Any such serious adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. In the context of our ongoing clinical trial, we report adverse events to the FDA in accordance with IDE regulations and to other relevant regulatory authorities in accordance with applicable national and local regulations. Any corrective action, whether voluntary or involuntary, and either pre- or post-market, needed to address any serious adverse events will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Our medical device products, once approved, may in the future be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

If our products are approved for commercialization, the FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. A government mandated or voluntary recall by us or one of our partners could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects, or other deficiencies and issues. Recalls of any of our commercialized products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations, and financial condition, which could impair our ability to produce our products in a cost effective and timely manner in order to meet our customers' demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits.

If we obtain approval for our products, we may be subject to enforcement action if we engage in improper marketing or promotion of our products.

We are not permitted to promote or market our investigational products. After approval, our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or off label, use. Surgeons may use our products off label, as the FDA does not restrict or regulate a surgeon's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or training constitutes promotion of an off label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine, or criminal penalties. It is also possible that other federal, state, or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products could be impaired. In addition, the off label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us, and harm our reputation.

Table of Contents

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 payers 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.

Legislative or regulatory reform of the healthcare systems in which we operate may affect our ability to commercialize our product candidates and could adversely affect our business.

The government and regulatory authorities in the United States, the European Union, and other markets in which we plan to commercialize our product candidates may propose and adopt new legislation and regulatory requirements relating to the approval, CE marking, manufacturing, promotion, or reimbursement of medical device and biologic products. It is impossible to predict whether legislative changes will be enacted or applicable regulations, guidance, or interpretations changed and what the impact of such changes, if any, may be. Such legislation or regulatory requirements, or the failure to comply with such, could adversely impact our operations and could have a material adverse effect on our business, financial condition, and results of operations.

For example, on September 26, 2012, the European Commission adopted a package of legislative proposals designed to replace the existing regulatory framework for medical devices in the European Union. These proposals are intended to strengthen the medical devices rules in the European Union. On June 17, 2016, the Dutch Presidency of the Council of the European Union formally informed the Council of Ministers of the agreement that was reached on May 25, 2016 with the European Parliament as part of the discussion concerning the text of the proposed Medical Devices Regulation (“MDR”) and the In Vitro Diagnostic Medical Devices Regulation (“IVDR”). On February 22, 2017, after finalization of a final linguistic review of the texts and the last revisions, the final text of the MDR and IVDR were published on the Council of the European Union's website. The regulations are now anticipated to be definitively adopted by the Council and the European Parliament by the end of the March 2017. The regulations, which will substantially impact medical devices manufacturers, will be applicable from May 2020 for the MDR and May 2022 for the IVDR. When adopted and applicable, the proposed MDR may prevent or delay the CE marking of our products under development or impact our ability to modify our currently CE marked products on a timely basis.

Similarly, in the United States, legislative changes have been enacted in the past and further changes are proposed that would impact the Affordable Care Act. These new laws may result in additional reductions in Medicare and other healthcare funding. Beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, on average, to 2025. It is likely that federal and state legislatures within the United States and foreign

governments will continue to consider changes to existing healthcare legislation. The Affordable Care Act has faced ongoing legal challenges, including litigation seeking to invalidate some of or all of the law or the manner in which it has been implemented, and Congressional leaders and the recently elected President have stated that they intend to repeal or modify some or all of the provisions of the Affordable Care Act, as well as make additional changes to portions of Medicare and Medicaid. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. Because of the continued uncertainty about the effects, implementation, and potential repeal or modification of the Affordable Care Act and other federal healthcare legislation, we cannot quantify or predict with any certainty the likely impact of the Affordable Care Act, its amendment or repeal, or any alternative or related legislation, or any implementation of any such legislation, on our business model, prospects, financial condition, and results of operations.

Table of Contents

In addition, in June 2016, eligible members of the electorate in the United Kingdom decided by referendum to exit the European Union, which is commonly referred to as Brexit. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the referendum could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union. We are currently planning to open sites for The INSPIRE Study and anticipate that we will be subject to applicable U.K. regulations. Because of the continued uncertainty about the effects, implementation, or potential repeal of Brexit, we cannot quantify or predict with any certainty the likely impact of Brexit or related legislation on our business model, prospects, financial condition, and results of operations.

These and other legislative and regulatory changes that have been or may be proposed in the future may impact our ability to successfully commercialize our product candidates.

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

To date, we have manufactured our Neuro-Spinal Scaffold implant 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 implant 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 for 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.

Risks Related to Our Intellectual Property

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 implant 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.

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 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.

Table of Contents

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.

Risks Related to our Dependence on Third Parties

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.

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.

If the third parties on which we rely to conduct our laboratory testing, animal, and human clinical trials do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our products.

We have been, and will continue to be, dependent on third party CROs, medical institutions, investigators, and contract laboratories to conduct certain of our laboratory testing, animal and human clinical studies. We are responsible for confirming that each of our clinical trials is conducted in accordance with our approved plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on 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 preclinical development activities or clinical trials may be extended,

Table of Contents

delayed, suspended, or terminated, and we may not be able to obtain regulatory approval or successfully commercialize our products on a timely basis, if at all, and our business, operating results, and prospects may be adversely affected.

Risks Related to Employee Matters and Managing Growth

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.

Risks Related to Litigation and Legal Compliance

We are subject to lawsuits, 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 implant. That lawsuit was dismissed with prejudice in April 2015. Plaintiffs filed an appeal of that dismissal to the United States Court of Appeals for the First Circuit. On January 9, 2017, the Court of Appeals issued an order and opinion affirming the dismissal of all claims with prejudice. The time for filing a petition for a writ of certiorari to the United States Supreme Court has not yet expired. If a petition for a writ of certiorari is filed, we cannot provide any assurance that we will be successful in defending against such an appeal or, if the dismissal is overturned, in defending the underlying lawsuit. Nor can we be certain that insurance proceeds will be sufficient to cover any liability under such claims. Additionally, we may face additional lawsuits, including class action or securities derivative lawsuits. We are also involved in litigation with our former Chairman, Chief Executive Officer, and Chief Financial Officer. We were previously the subject of a securities derivative lawsuit, which was dismissed in January 2017, and the deadline for appealing that decision has passed. See "Legal Proceedings" below for further information regarding our litigation.

Table of Contents

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. Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation.

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 terms, 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.

Our relationships with customers and third party payers will be subject to applicable anti-kickback, fraud and abuse, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm, and diminished profits and future earnings.

Healthcare providers, physicians, and third party payers will play a primary role in the recommendation and use of our products and any other product candidates for which we obtain marketing approval. Our future arrangements with healthcare providers, physicians, and third party payers may expose us to broadly applicable fraud and abuse and other

healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order, or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties;

- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

Table of Contents

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered products to report payments and other transfers of value to physicians and teaching hospitals; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws and transparency statutes, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payers, including private insurers.

Some state laws require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require product manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment, or restructuring of our operations could adversely affect our financial results. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs.

Risks Related to Investment in Our Securities

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;

Table of Contents

· 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, 2016, there were outstanding warrants to purchase 3,391,439 shares of our common stock, and outstanding options to purchase 3,193,785 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 Nasdaq Global Market.

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.

Table of Contents

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, which is used primarily for corporate, manufacturing, and research and development functions. The lease commenced in November 2011, and is for an initial term of six years and three months, with one five year extension exercisable by us. In March 2016, we entered into a short-term lease with CRISPR Therapeutics, as subtenant, to sub-lease 5,233 square feet of our building. This sub-lease was terminated on January 31, 2017. We believe this facility is adequate to meet our current needs and that additional space could be available on commercially reasonable terms as needed.

Item 3. LEGAL PROCEEDINGS

Lawsuits 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, and 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 related to Mr. Reynolds’s allegations that we and the Board of Directors 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 that he did not receive. On January 9, 2014, we, along with the directors named in the counterclaims, filed our answer. Discovery has now been completed and our motion for summary judgment on all counts of the complaint and Reynolds’ opposition to the motion for summary judgment was filed with the court on March 3, 2017.

We intend to continue to defend ourselves against these claims and, to date, we have not recorded any provision for losses that may arise.

On July 22, 2016, Mr. Reynolds filed a lawsuit against us, certain present and former members of our Board of Directors and an employee of ours in Hillsborough County Superior Court, Southern District, Hillsborough County, New Hampshire (Reynolds v. InVivo Therapeutics Holdings Corp, et al.) alleging defamation, conspiracy, and tortious interference, and seeking monetary damages. In August 2016, the lawsuit was removed to the United States District Court for the District of New Hampshire. We filed a motion to dismiss this action and after oral argument on November 28, 2016, the Court on November 30, 2016 issued an order dismissing the case for lack of personal jurisdiction. The judgment was entered on the docket on December 1, 2016, and the deadline for appealing that decision has passed.

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 us 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™ implant. The plaintiff sought class certification for purchasers of our common stock during the period from April 5, 2013 through August 26, 2013 and unspecified damages. On April 3, 2015, the United States District Court for the District of Massachusetts dismissed the plaintiff’s claim with prejudice.

On May 4, 2015, the plaintiff filed a notice of appeal of this decision. Following the submission of briefs by the parties, the Court of Appeals heard oral arguments on April 6, 2016. On January 9, 2017, the Court of Appeals for the

Table of Contents

First Circuit issued an order and opinion affirming the dismissal of the Securities Class Action with prejudice. Plaintiff has until April 10, 2017 to file a petition for certiorari to the United States Supreme Court.

We intend to continue to defend ourselves against these claims and, to date, we have not recorded any provision for losses that may arise.

On January 23, 2015, Shawn Luger, a purported shareholder of ours, sent us a letter (the "Shareholder Demand") 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. Our Board of Directors completed its investigation of the matters raised in the Shareholder Demand and voted unanimously not to pursue any litigation against any current or former director, officer, or employee of ours with respect to the matters set forth in the Shareholder Demand.

On August 14, 2015, Mr. Luger filed a shareholder derivative lawsuit in the Superior Court of Suffolk County for the Commonwealth of Massachusetts on our behalf against certain present and former board members and company executives alleging the same breaches of fiduciary duties purportedly set forth in the Shareholder Demand. On February 5, 2016, the Superior Court of Suffolk County dismissed the plaintiff's claims with prejudice. On March 4, 2016, the plaintiff filed a notice of appeal of this decision. Following the submission of brief by the parties, the Appeals Court heard oral argument on December 13, 2016. On January 3, 2017, the Appeals Court issued an order and opinion affirming the dismissal of all claims with prejudice. The time period for Mr. Luger to appeal the Appeals Court's judgment has expired.

In addition, we received investigation subpoenas from the Boston Regional Office of the SEC and the Massachusetts Securities Division of the Secretary of the Commonwealth of Massachusetts ("MSD") requesting corporate documents concerning, among other topics, the allegations raised by the Securities Class Action and the Shareholder Demand. On October 21, 2015, after responding to the SEC's subpoena, we received a letter from the SEC notifying us that it had concluded its investigation of us and that it did not intend to recommend an enforcement action against us. We responded to the MSD's subpoena on September 22, 2014 and October 8, 2014. On February 18, 2015, we received a second subpoena from the MSD requesting additional documents and information related to the same topics. We responded to this second subpoena on March 24, 2015. We have not further heard from the MSD since we responded to this last subpoena.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

42

Table of Contents

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our common stock is currently listed for trading on the Nasdaq Global Market under the symbol "NVIV." From October 29, 2010 through April 16, 2015, our common stock was quoted on the OTCQB under the same symbol. The following table shows the high and low bid prices for our common stock for our two most recent fiscal years:

Fiscal Quarter Ended	High Bid	Low Bid
December 31, 2016	$ 6.65	$ 4.05
September 30, 2016	$ 7.77	$ 5.63
June 30, 2016	$ 6.99	$ 5.51
March 31, 2016	$ 9.85	$ 3.66

Fiscal Quarter Ended	High Bid	Low Bid
December 31, 2015	$ 11.80	$ 6.55
September 30, 2015	$ 17.65	$ 7.33
June 30, 2015	$ 19.68	$ 11.20
March 31, 2015	$ 12.48	$ 5.04

These market quotations reflect inter-dealer prices, without retail mark-up, markdown, or commissions and may not necessarily represent actual transactions. The prices give effect to the 1-for-4 reverse stock split of our outstanding shares of common stock that occurred on April 8, 2015. The high and low bid prices listed have been rounded up to the nearest penny.

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 our 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 3, 2017, we had approximately 320 stockholders of record. This figure does not reflect persons or entities that hold their stock in nominee or “street” name through various brokerage firms.

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 deemed incorporated by reference into any future filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that we specifically incorporate it by reference into any such filing.

Table of Contents

The graph below compares the cumulative total returns of our common stock to the cumulative returns of the NASDAQ Composite index and the NASDAQ Biotechnology index for the period from December 31, 2011 through December 31, 2016. This graph assumes an investment of $100 on December 31, 2011 in our common stock and in each of the comparative indices and assumes reinvestment of dividends, if any.

The comparisons shown in the graph below are based on historical data. We caution that the stock price performance showing in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among InVivo Therapeutics Holdings Corp, the NASDAQ Composite Index,

and the NASDAQ Biotechnology Index

*$100 invested on December 31, 2011 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

	December 31,					
	2011	2012	2013	2014	2015	2016
InVivo Therapeutics Holdings Corp	$ 100.00	$ 63.27	$ 83.49	$ 48.00	$ 65.45	$ 38.18
NASDAQ Composite	$ 100.00	$ 116.41	$ 165.47	$ 188.69	$ 200.32	$ 216.54
NASDAQ Biotechnology	$ 100.00	$ 134.68	$ 232.37	$ 307.67	$ 328.76	$ 262.08

44

Table of Contents

Item 6. SELECTED FINANCIAL DATA

The selected financial data presented below is derived from our audited consolidated financial statements. You should read the 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 of this Annual Report on Form 10-K and in the financial statements, related notes, and other financial information included elsewhere in this Annual Report on Form 10-K. Unless otherwise indicated, all amounts in this Item 6 are presented in thousands, except share and per share data. All share amounts give effect to the 1-for-4 reverse stock split of our outstanding shares of common stock that occurred on April 8, 2015.

InVivo Therapeutics Holdings Corp.

	Year Ended December 31,				
Consolidated Statement of Operations (in thousands)	2016	2015	2014	2013	2012
Operating expenses:					
Research and development	$ 12,557	$ 10,058	$ 10,273	$ 10,533	$ 6,376
General and administrative	11,506	12,340	7,566	8,472	6,403
Total operating expenses	24,063	22,398	17,839	19,005	12,779
Operating loss	(24,063)	(22,398)	(17,839)	(19,005)	(12,779)
Other income (expense):					
Interest income	187	60	5	15	35
Interest expense	(155)	(172)	(136)	(130)	(72)
Modification of warrants	—	—	—	(765)	—
Derivatives gain (loss)	593	(10,804)	(376)	(18,871)	17,480
Other income (expense), net	625	(10,916)	(507)	(19,751)	17,443
Net income (loss)	$ (23,438)	$ (33,314)	$ (18,346)	$ (38,756)	$ 4,664
Net income (loss) per share, basic	$ (0.76)	$ (1.26)	$ (0.83)	$ (2.10)	$ 0.30
Net income (loss) per share, diluted	$ (0.76)	$ (1.26)	$ (0.83)	$ (2.10)	$ 0.26
Weighted average number of common shares outstanding, basic	31,025,585	26,461,374	22,080,761	18,497,922	15,806,725
Weighted average number of common shares outstanding, diluted	31,025,585	26,461,374	22,080,761	18,497,922	17,979,855

As of December 31,

Condensed Consolidated Balance Sheet (in thousands)	2016	2015	2014	2013	2012
Cash, cash equivalents and marketable securities	$ 33,041	$ 20,194	$ 13,459	$ 13,980	$ 12,825
Working capital	29,005	17,427	6,169	12,334	(3,221)
Total assets	34,784	21,792	16,693	17,096	16,062
Long-term liabilities	987	1,551	1,991	1,938	1,581
Derivative warrant liability	1,314	1,907	7,224	—	14,585
Accumulated deficit	(157,007)	(133,569)	(100,255)	(81,909)	(43,153)
Stockholder's equity (deficit)	28,949	16,929	5,918	12,890	(2,310)

We have derived our statements of operations data for the years ended December 31, 2013 and 2012 and our balance sheet data as of December 31, 2014, 2013, and 2012 from our audited financial statements which are not included in this Annual Report on Form 10-K. We have derived our statements of operations data for the years ended December 31, 2016, 2015 and 2014 and our balance sheet data as of December 31, 2016 and 2015 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).

Table of Contents

Supplementary Quarterly Financial Data (Unaudited—In thousands)

	Quarter Ended			
	December 31, 2016	September 30, 2016	June 30, 2016	March 31, 2016
Operating expenses:				
Research and development	$ 3,900	$ 3,294	$ 2,795	$ 2,568
General and administrative	2,932	2,584	2,991	2,999
Total operating expenses	6,832	5,878	5,786	5,567
Operating loss	(6,832)	(5,878)	(5,786)	(5,567)
Other income (expense):				
Interest income	47	50	36	54
Interest expense	(31)	(32)	(29)	(63)
Derivatives gain (loss)	1,381	(336)	595	(1,047)
Other income (expense), net	1,397	(318)	602	(1,056)
Net loss	$ (5,435)	$ (6,196)	$ (5,184)	$ (6,623)

	Quarter Ended			
	December 31, 2015	September 30, 2015	June 30, 2015	March 31, 2015
Operating expenses:				
Research and development	$ 2,777	$ 2,432	$ 2,546	$ 2,303
General and administrative	2,481	3,437	3,214	3,208
Total operating expenses	5,258	5,869	5,760	5,511
Operating loss	(5,258)	(5,869)	(5,760)	(5,511)
Other income (expense):				
Interest income	48	9	2	1
Interest expense	(67)	(39)	(32)	(34)
Derivatives gain (loss)	544	3,591	(4,653)	(10,286)
Other income (expense), net	525	3,561	(4,683)	(10,319)
Net loss	$ (4,733)	$ (2,308)	$ (10,443)	$ (15,830)

Table of Contents

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 also the "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.

All share amounts presented in this Item 7 give effect to the 1-for-4 reverse stock split of our outstanding shares of common stock that occurred on April 8, 2015.

Introduction

This Management's Discussion and Analysis of our financial condition and results of operations is 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 our 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 ("SCIs"). Our mission is to redefine the life of the SCI patient, and we are developing treatment options intended to provide meaningful improvement in patient outcomes following SCI. Our approach to treating acute SCIs is based on our investigational Neuro-Spinal ScaffoldTM implant, a bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord and is intended to treat acute SCI. We believe the Neuro-Spinal Scaffold is the only SCI therapy in development focused solely on treating acute SCI directly at the epicenter of the injury. The Neuro-Spinal Scaffold incorporates intellectual property licensed under an exclusive,

worldwide license from Boston Children's Hospital ("BCH") and the Massachusetts Institute of Technology ("MIT"). We are continually evaluating other technologies and therapeutics that may be complementary to our development of the Neuro-Spinal Scaffold or offer the potential to bring us closer to our goal of redefining the life of the SCI patient. We have also entered into exclusive license/assignment agreements with the University of California, San Diego and James Guest, M.D., Ph.D. covering delivery methods and devices for our preclinical Therapeutic Trails™ injection program.

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. However, expenditures on research and development programs are subject to many uncertainties, including whether we develop our products with a partner or independently, or whether we acquire products from third parties. 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 research and development 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 implant, our future research and development 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 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.

Table of Contents

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.

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 our management make certain assumptions and estimates and, in connection therewith, adopt certain accounting policies. Our significant accounting policies are set forth in Note 2, “Significant Accounting Policies”, in the Notes to Consolidated Financial Statements in Item 8 of this Annual Report on Form 10-K. Of those policies, we believe that the policies discussed below may involve the highest degree of judgment and may be the most critical to an accurate reflection of our financial condition and results of operations.

Stock Based Compensation

Our stock options are granted with an exercise price set at the fair market value of our common stock on the date of grant. Our stock options generally expire ten years from the date of grant and 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 our statement of operations over the service period based on a measure 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 a compensation cost on a straight line basis over the requisite service period of the award, which is generally the vesting period. We use historical data, as well as subsequent events occurring prior to the preparation of our consolidated financial statements, to estimate option exercises and employee departures within the valuation model. The expected term of any 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 expected term of 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 use 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 such derivative warrant liabilities 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 Expense

Our research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

· employee related expenses, including salaries, benefits, travel, and stock based compensation expense;

Table of Contents

- expenses incurred under agreements with contract research organization ("CROs"), and clinical sites that conduct our clinical studies;

- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and other supplies;

- costs associated with our research platform and preclinical activities;

- costs associated with our regulatory, quality assurance, and quality control operations; and

- amortization of intangible assets.

Our research and development costs are expensed as incurred. We are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrued expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

General and Administrative Expense

General and administrative expenses consist primarily of salaries and related costs for personnel, including stock-based compensation and travel expenses for our employees in executive, operational, finance, legal, business development, commercial, and human resource functions. Other general and administrative expenses include facility-related costs, professional fees for accounting, tax and legal and consulting services, directors' fees and expenses associated with obtaining and maintaining patents.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates. Additionally, if and when we believe a regulatory approval of the first product candidate appears likely, we anticipate an increase in payroll and related expenses as a result of our preparation for commercial operations, especially as it

relates to the sales and marketing of our product candidates.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-15, Presentation of Financial Statements—Going Concern, on disclosure of uncertainties about an entity's ability to continue as a going concern. This guidance addresses management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosures. The guidance is effective for fiscal years ending after December 15, 2016 including interim reporting periods within each annual reporting period, with early adoption permitted. We adopted this guidance as of December 31, 2016. The adoption of ASU 2014-15 impacted our presentation and disclosure only and did not have any impact on financial position or results of operations.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (“ASU 2014-09”) to provide updated guidance on revenue recognition. ASU 2014-09 requires a company to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled to in exchange for those goods or services. In doing so, companies may need to use more judgment and make more estimates than under today’s guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. In August 2015, the FASB issued ASU No. 2015-14, Revenue from

Table of Contents

Contracts with Customers (Topic 606): Deferral of the Effective Date, which deferred the effective date of ASU 2014-09 by one year. Accordingly, ASU 2014-09 is effective for public business entities for annual reporting periods beginning after December 15, 2017, including interim reporting periods within each annual reporting period. In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross Versus Net), which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients, which relates to disclosures of remaining performance obligations, as well as other amendments to guidance on collectability, non-cash consideration and the presentation of sales and other similar taxes collected from customers. These standards have the same effective date and transition date of December 15, 2017. Currently, this guidance is not applicable to us as we are still in the research and development stage. However, we will continue to evaluate the impact of adopting ASU 2014-09 on our consolidated financial statements when we begin to generate revenue.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The guidance in this ASU supersedes the leasing guidance in Topic 840, Leases. Under the new guidance, lessees are required to recognize lease assets and lease liabilities on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance leases or operating leases, with classification affecting the pattern of expense recognition in the statement of operations. The new standard is effective for annual reporting periods beginning after December 15, 2018, including interim reporting periods within each annual reporting period. We are currently evaluating the impact of the adoption of this ASU on our financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (“ASU 2016-09”) to require changes to several areas of employee share-based payment accounting in an effort to simplify share-based reporting. The update revises requirements in the following areas: minimum statutory withholding, accounting for income taxes, forfeitures, and intrinsic value accounting for private entities. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016, including interim reporting periods within each annual reporting period. We will adopt this standard on January 1, 2017, and the adoption is not expected to have a material impact on our consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, Classification of Certain Cash Receipts and Cash Payments (“ASU 2016-15”), to address how certain cash receipts and cash payments are presented and classified in the statement of cash flows in an effort to reduce existing diversity in practice. The update includes eight specific cash flow issues and provides guidance on the appropriate cash flow presentation for each. ASU 2016-15 is effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within each annual reporting period. We do not expect the adoption of this guidance to have a material impact on our financial statements.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash to clarify how entities should present restricted cash and restricted cash equivalents in their statements of cash flows.

Under this new update, entities are required to show the changes in the total of cash, cash equivalents, restricted cash and restricted cash equivalents in their statements of cash flows. This guidance will be applied retrospectively and is effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within each annual reporting period. We are currently evaluating the impact of the adoption of this ASU on our the financial statements.

Results of Operations

Comparison of the Years Ended December 31, 2016 and 2015 (in thousands, except share and per share amounts)

Research and Development Expenses

Research and development expenses increased by $2,499 to $12,557 for the year ended December 31, 2016 from $10,058 for the year ended December 31, 2015. This increase is primarily attributable to an increase in clinical trial costs of $811 due to an increase in the number of patients in The INSPIRE Study and the opening of additional clinical trial sites, and higher contract services costs of $439 associated with research development initiatives. The increase is also due to compensation-related expenses of $656, intellectual property costs of $229, consulting fees of $110,

Table of Contents

recruiting costs of $102, and packaging and lab-related expenses of $123.

General and Administrative Expenses

General and administrative expenses decreased by $834 to $11,506 for the year ended December 31, 2016 from $12,340 for the year ended December 31, 2015. This decrease in general and administrative expenses is attributable to a decrease in legal expenses of $1,737 as well as decreases in public and investor relations costs of $116 and overhead expense of $93. These decreases are partially offset by increases in compensation-related expenses of $342, stock-based compensation expense of $292, convention and meeting costs of $178, recruiting related costs of $162, insurance expense of $118, and consulting fees of $54.

Interest Income

Interest income increased by $127 to $187 for the year ended December 31, 2016 from $60 for the year ended December 31, 2015. This increase is due to a higher average balance of funds in our short-term investments.

Interest Expense

Interest expense decreased by $17 to $155 for the year ended December 31, 2016 from $172 for the year ended December 31, 2015. This decrease in interest expense is primarily due to lower average borrowings.

Derivatives Gain (Loss)

The derivatives gain for the year ended December 31, 2016 is $593 compared to a loss of $10,804 for the year ended December 31, 2015. The gain of $593 for the year ended December 31, 2016 reflects the decrease in the fair value of our derivative warrant liability due primarily to the decrease in the fair value of the underlying common stock, as well as the decreasing term to expiration of the warrants. In 2015, the loss was driven primarily by an increase in the value of our common stock.

Comparison of the Years Ended December 31, 2015 and 2014 (in thousands, except share and per share amounts)

Research and Development Expenses

Research and development expenses decreased by $215 to $10,058 for the year ended December 31, 2015 from $10,273 for the year ended December 31, 2014. After adjusting for the $621 insurance settlement related to business interruption, research and development expenses were $10,894 for 2014. The decrease in adjusted research and development expenses for 2015 of $836 was primarily attributable to decreases in consulting costs of $612, testing costs of $375, packaging and lab supplies of $359, compensation-related expense attributable to the 2014 reduction in force of $564, and other various expenses of $338. These reductions were partly offset by higher clinical trial costs of $729, stock compensation expense of $147, and bonus expense of $536. Bonus expense was higher in 2015 compared to 2014 due to the fact that in 2014 the accrual, which related to the 2013 bonus accrual, was reversed because of the Company’s decision not to pay out 2013 bonuses.

General and Administrative Expenses

General and administrative expenses increased by $4,774 to $12,340 for the year ended December 31, 2015 from $7,566 for the year ended December 31, 2014. This increase in general and administrative expenses for 2015 was primarily attributable to increases in legal costs of $1,361, related to the Securities and Exchange Commission (“SEC”) and Massachusetts Securities Division of the Secretary of the Commonwealth of Massachusetts inquiries as well as the Securities Class Action lawsuit, stock compensation expense of $1,789, investor relation expense and NASDAQ listing fees of $425, Board and audit fees of $251, consulting costs of $387, and other various expenses of $561.

Table of Contents

Interest Income

Interest expense increased by $55 to $60 for the year ended December 31, 2015 from $5 for the year ended December 31, 2014. This increase was due to interest earned on our short-term investments.

Interest Expense

Interest expense increased by $36 to $172 for the year ended December 31, 2015 from $136 for the year ended December 31, 2014. This increase in interest expense was primarily due to the amortization of the premium or discount values of our short-term investments compared to the maturity value.

Derivatives Gain (Loss)

Derivative losses decreased by $10,428 to a loss of $10,804 for the year ended December 31, 2015 from a loss of $376 for the year ended December 31, 2014. The loss of $10,804 for the year ended December 31, 2015 reflects the increase in the fair value of our derivative warrant liability, which was due primarily to the increase in the fair value of the underlying common stock, the decreasing term to expiration of the warrants as well as the exercise of approximately 78% of the outstanding warrants during 2015.

Liquidity and Capital Resources (in thousands, except share and per share figures)

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, 2016, our accumulated deficit was $157,007.

At December 31, 2016, we had total assets of $34,784, total liabilities of $5,835, and total stockholders' equity of $28,949. We recorded a net loss of $23,438 for the year ended December 31, 2016. 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 fund our operations and 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 for other working capital requirements. We also expect that we will need to raise additional capital 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. In January 2015, we closed a registered direct offering of an aggregate of 2,000,000 shares of our common stock, resulting in net proceeds of approximately $11,038. In July 2015, we entered into a Sales Agreement with Cowen and Company, LLC ("Cowen") allowing us to issue and sell from time to time up to $50,000 in shares of our common stock through an "at the market" equity offering program (the "ATM"). In 2015, we raised approximately $3,442, through the ATM, net of a 3% commission on the gross proceeds from the sale of shares under the ATM due to Cowen, as our sales agent in the ATM, and other transaction related expenses. We did not make any sales under the Sales Agreement in 2016 and the Sales Agreement was terminated in March 2016. In March 2016, we closed an underwritten public offering of an aggregate of 4,293,333 shares of common stock and warrants to purchase an aggregate of 2,146,666 shares of common stock at a price to the public of $7.49 per share of common stock and $0.01 per warrant. The net proceeds to the Company, after deducting underwriting discounts and offering expenses, were approximately $29,905. The warrants have a per share exercise price of $10.00, or approximately 133% of the public offering price of the common stock, are exercisable immediately, and expire on March 18, 2021. The Company intends to use the net proceeds from the offering to fund ongoing clinical trials and for general corporate purposes.

At December 31, 2016, our consolidated cash, cash equivalents, and marketable securities balance was $33,041. We believe our current cash, cash equivalents, and marketable securities are adequate to fund our operations into the beginning of the second quarter of 2018.

Table of Contents

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 has declared effective, a universal shelf registration statement which permits us to issue up to $100,000 worth of registered equity securities, of which we utilized $12,000 in our January 2015 offering and have utilized approximately $3,442 to date under our ATM, which was terminated in March 2016. Under this effective shelf registration, we also have the flexibility to issue registered securities, from time to time, in one or more additional offerings or other transactions with the size, price and terms to be determined at the time of issuance. In March 2016, we closed an underwritten public offering of an aggregate of 4,293,333 shares of common stock and warrants to purchase an aggregate of 2,146,666 shares of common stock, at a price to the public of $7.49 per share of common stock and $0.01 per warrant. The underwriting discount was 6% of the public offering price of the shares, or $0.45 per share and 0.0000006 per warrant. The warrants have an initial per share exercise price of $10.00 (133% of public offering price of the common stock) and will expire on March 18, 2021. 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.

We may pursue various other dilutive and non dilutive funding alternatives depending upon the results of our ongoing pivotal probable benefit study and the extent to which we require additional capital to proceed with development of some or all of our product candidates on expected timelines. The source, timing and availability of any future financing will depend principally upon market conditions and the status of our 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 to, among other things, delay, scale back or eliminate some or all of our research and product development programs, planned clinical trials, and capital expenditures or to license our potential products or technologies to third parties. We may alternatively engage in cost-cutting measures in an attempt to extend our cash resources as long as possible.

Net cash used in operating activities is comprised of our net losses, adjusted for non-cash expenses, and working capital requirements. Net cash used in operating activities for the year ended December 31, 2016 was $16,740, the most significant drivers of which were our net loss of $23,438, offsetting share-based compensation of $5,063 and change in accrued expenses of $1,471.

Net cash used in investing activities was $6,508 for the year ended December 31, 2016, attributable to the purchases of marketable securities of $18,916 and capital equipment of $107, partially offset by sales of marketable securities of $12,515.

Net cash provided by financing activities was $29,792 for the year ended December 31, 2016, consisting of the proceeds from issuances of common stock and warrants of $29,905 and proceeds from the exercises of stock options and Employee Stock Purchase Plan issuances of $282. These proceeds were partially offset by the repayment of loan principal of $395.

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, 2016, and the effects such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due		
In thousands	Total	Less than 1 year	1-3 years
Long-term debt	$ 1,275	$ 423	$ 852
Operating lease payments	2,377	1,289	1,088
Total	$ 3,652	$ 1,712	$ 1,940

Table of Contents

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 regarding our commitments.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK (in thousands)

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, cash equivalents, and marketable securities of $33,041, or 95% of our total assets at December 31, 2016, and $14,920, or 93% of our total assets at December 31, 2015. Interest income earned on these assets was $187 in 2016 and $60 in 2015. Our interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates. At December 31, 2016, our cash equivalents were primarily composed of money market accounts comprised of U.S. Treasury debt securities and repurchase agreements.

Table of Contents

Item 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Consolidated Financial Statements

SPECIAL NOTE

All share numbers and share prices presented in this Item 8 have been adjusted to reflect the 1 for 4 reverse stock split of the Company's common stock effected on April 8, 2015.

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

InVivo Therapeutics Holdings Corp. and Subsidiary

Cambridge, Massachusetts

We have audited the accompanying consolidated balance sheets of InVivo Therapeutics Holdings Corp. and Subsidiary (the “Company”) as of December 31, 2016 and 2015, and the related consolidated statements of operations, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2016. We also have audited InVivo Therapeutics Holdings Corp. and Subsidiary's internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013. InVivo Therapeutics Holdings Corp. and Subsidiary’s management is responsible for these financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management’s Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on these financial statements and schedules and an opinion on the Company's internal control over financial reporting 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting 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 audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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 consolidated financial statements referred to above present fairly, in all material respects, the financial position of InVivo Therapeutics Holdings Corp. and Subsidiary as of December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2016, in conformity with accounting principles generally accepted in the United States of America, and in our opinion, the related financial statement schedules, when considered in relation to the consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein. Also in our opinion, InVivo Therapeutics Holdings Corp. and Subsidiary maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013.

The accompanying financial statements have been prepared assuming that the Company will continue as a

Table of Contents

going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations which raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ RSM US LLP

Boston, MA

March 10, 2017

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated statements of operations, changes in stockholders' equity and cash flows of InVivo Therapeutics Holdings Corp. and subsidiary for the year 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 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 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 audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the results of operations and cash flows of InVivo Therapeutics Holdings Corp. and subsidiary for the year ended December 31, 2014, in conformity with accounting principles generally accepted in the United States of America.

/s/ Wolf & Company, P.C.

Boston, Massachusetts

March 11, 2015

Table of Contents

InVivo Therapeutics Holdings Corp.

Consolidated Balance Sheets

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

	December 31, 2016	2015
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 21,464	$ 14,920
Restricted cash	361	361
Marketable securities	11,577	5,274
Prepaid expenses and other current assets	451	184
Total current assets	33,853	20,739
Property, equipment and leasehold improvements, net	510	938
Other assets	421	115
Total assets	$ 34,784	$ 21,792
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 1,011	$ 521
Loan payable, current portion	423	395
Derivative warrant liability	1,314	1,907
Deferred rent, current portion	141	115
Accrued expenses	1,959	374
Total current liabilities	4,848	3,312
Loan payable, net of current portion	852	1,275
Deferred rent, net of current portion	135	276
Total liabilities	5,835	4,863
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.00001 par value, authorized 100,000,000 shares, issued and outstanding 32,044,087 shares at December 31, 2016; and authorized 50,000,000 shares, issued and outstanding 27,555,948 shares at December 31, 2015	1	1
Additional paid-in capital	185,955	150,497
Accumulated deficit	(157,007)	(133,569)
Total stockholders' equity	28,949	16,929
Total liabilities and stockholders' equity	$ 34,784	$ 21,792

See notes to the consolidated financial statements.

59

Table of Contents

InVivo Therapeutics Holdings Corp.

Consolidated Statements of Operations

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

	Year Ended December 31,		
	2016	2015	2014
Operating expenses:			
Research and development	$ 12,557	$ 10,058	$ 10,273
General and administrative	11,506	12,340	7,566
Total operating expenses	24,063	22,398	17,839
Operating loss	(24,063)	(22,398)	(17,839)
Other income (expense):			
Interest income	187	60	5
Interest expense	(155)	(172)	(136)
Derivatives gain (loss)	593	(10,804)	(376)
Other income (expense), net	625	(10,916)	(507)
Net loss	$ (23,438)	$ (33,314)	$ (18,346)
Net loss per share, basic and diluted	$ (0.76)	$ (1.26)	$ (0.83)
Weighted average number of common shares outstanding, basic and diluted	31,025,585	26,461,374	22,080,761

See notes to the consolidated financial statements.

Table of Contents

InVivo Therapeutics Holdings Corp.

Consolidated Statements of Changes in Stockholders' Equity

	Common Stock Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance as of December 31, 2013	19,693,434	$ 1	$ 94,798	$ (81,909)	$ 12,890
Share-based compensation expense	—	—	2,730	—	2,730
Issuance of common stock in public offering	3,500,312	—	7,770	—	7,770
Issuance of common stock for services	74,626	—	477	—	477
Issuance of common stock upon exercise of warrants	9,975	—	12	—	12
Issuance of common stock upon exercise of stock options	132,900	—	212	—	212
Issuance of common stock to 401(k) plan	41,753	—	173	—	173
Net loss	—	—	—	(18,346)	(18,346)
Balance as of December 31, 2014	23,453,000	1	106,172	(100,255)	5,918
Share-based compensation expense	—	—	4,666	—	4,666
Issuance of common stock in public offerings	2,388,245	—	14,480	—	14,480
Issuance of common stock upon exercise of warrants	1,379,575	—	7,789	—	7,789
Issuance of common stock upon exercise of stock options	316,177	—	1,068	—	1,068
Fair value of derivative warrant liability reclassified to additional paid-in capital	—	—	16,121	—	16,121
Fractional shares issued due to reverse stock split	1,514	—	—	—	—
Issuance of common stock to 401(k) plan	17,437	—	201	—	201
Net loss	—	—	—	(33,314)	(33,314)
Balance as of December 31, 2015	27,555,948	1	150,497	(133,569)	16,929
Share-based compensation expense	—	—	5,063	—	5,063
Issuance of common stock and warrants in public offerings, net of $2,040 issuance costs	4,293,333	—	29,905	—	29,905
Issuance of common stock for services	365	—	—	—	—
Issuance of common stock upon cashless exercise of warrants	4,979	—	—	—	—

Issuance of common stock upon exercise of stock options	135,205	—	191	—	191
Issuance of common stock under ESPP	16,729		91		91
Issuance of common stock to 401(k) plan	37,528	—	208	—	208
Net loss	—	—	—	(23,438)	(23,438)
Balance as of December 31, 2016	32,044,087	$ 1	$ 185,955	$ (157,007)	$ 28,949

See notes to the consolidated financial statements.

Table of Contents

InVivo Therapeutics Holdings Corp.

Consolidated Statements of Cash Flows

(In thousands)

	Years Ended December 31,		
	2016	2015	2014
Cash flows from operating activities:			
Net loss	$ (23,438)	$ (33,314)	$ (18,346)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	553	689	752
Derivatives (gain) loss	(593)	10,804	376
Common stock issued to 401(k) plan	208	201	173
Common stock issued for services	—	—	477
Share-based compensation expense	5,063	4,666	2,730
Other non-cash investment activities	98	—	—
Changes in operating assets and liabilities:			
Restricted cash	—	61	180
Prepaid expenses	(267)	888	(363)
Insurance receivable	—	—	(689)
Other assets	(324)	3	4
Accounts payable	489	(48)	(330)
Accrued expenses	1,471	(279)	(248)
Net cash used in operating activities	(16,740)	(16,329)	(15,284)
Cash flows from investing activities:			
Purchases of marketable securities	(18,916)	(5,274)	—
Sales of marketable securities	12,515	—	—
Non-cash disposals of property and equipment	—	—	45
Purchases of property and equipment	(107)	(5)	(47)
Net cash used in investing activities	(6,508)	(5,279)	(2)
Cash flows from financing activities:			
Proceeds from exercise of stock options	191	1,068	212
Proceeds from issuance of stock under ESPP	91	—	—
Proceeds from exercise of warrants	—	7,789	12
Repayment of note payable	—	(18)	(56)
Principal payments on capital lease obligation	—	—	(21)
Repayment of loan payable	(395)	(250)	—
Proceeds from issuance of common stock and warrants	29,905	14,480	14,618
Net cash provided by financing activities	29,792	23,069	14,765
Increase (decrease) in cash and cash equivalents	6,544	1,461	(521)

Cash and cash equivalents at beginning of period	14,920	13,459	13,980
Cash and cash equivalents at end of period	$ 21,464	$ 14,920	$ 13,459
Supplemental disclosure of cash flow information and non-cash investing and financing activities:			
Cash paid for interest	$ 103	$ 121	$ 132
Cash paid for taxes	$ —	$ —	$ —
Fair value of warrants issued in connection with underwriting agreement	$ —	$ —	$ 6,848
Cashless exercise of equity-classified warrants to common stock	$ 90	$ 251	$ —
Reclassification of derivative warrant liability to additional paid-in capital	$ —	$ 16,121	$ —

See notes to the consolidated financial statements.

Table of Contents

InVivo Therapeutics Holdings Corp.

Notes to Consolidated Financial Statements

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

1. NATURE OF OPERATIONS AND GOING CONCERN

Business

InVivo Therapeutics Holdings Corp. (the "Company") is a pioneering biomaterials and biotechnology company with a focus on the treatment of spinal cord injuries ("SCIs"). The Company's proprietary technologies incorporate intellectual property that is licensed under an exclusive, worldwide 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, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets, and raising capital. The Company has historically financed its operations primarily through the sale of equity-related securities. At December 31, 2016, the Company has consolidated cash, cash equivalents, and marketable securities of $33,041. The Company has not achieved profitability and may not be able to realize sufficient revenue to achieve or sustain profitability in the future. The Company does not expect to be profitable in the next several years, but rather expects to incur additional operating losses. The Company has limited liquidity and capital resources and must obtain significant additional capital resources in order to sustain its product development efforts, for acquisition of technologies and intellectual property rights, for preclinical and clinical testing of its 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. The Company expects that it will need additional capital to fund its operations, which it 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.

Going Concern

The Company’s financial statements as of December 31, 2016 were prepared under the assumption that the Company will continue as a going concern. At December 31, 2016, the Company had cash, cash equivalents, and marketable securities of $33,041. Given the Company’s development plans, it estimates cash resources will be sufficient to fund its operations into the beginning of the second quarter of 2018. This estimate is based on assumptions that may prove to be wrong; expenses could prove to be significantly higher, leading to a more rapid consumption of the Company’s existing resources.

The Company’s ability to continue as a going concern depends on its ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce expenditures, and, ultimately, to generate revenue. If the Company is unable to continue as a going concern, it may have to liquidate its assets and may receive less than the value at which those assets are carried on its audited financial statements, and it is likely that investors will lose all or part of their investment. If the Company seeks additional financing to fund its business activities in the future and there remains substantial doubt about its ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to the Company on commercially reasonable terms or at all. Based on these factors, management determined that there is substantial doubt regarding the Company’s ability to continue as a going concern.

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:

Table of Contents

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 the financial statements and the reported amounts expensed 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. The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP.

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.

At December 31, 2016 and 2015, cash equivalents were comprised of money market funds and other short-term investments.

Cash and cash equivalents consist of the following:

	December 31,	
	2016	2015
Cash	$ 111	$ 116
Money market funds	21,353	14,804
Total cash and cash equivalents	$ 21,464	$ 14,920

Marketable securities

The Company invests its excess cash in fixed income instruments denominated and payable in U.S. dollars, including obligations of the U.S. government and its agencies, money market instruments, money market funds, corporate obligations, asset-backed securities, and municipal obligations. As of December 31, 2016, the Company's investment portfolio consists of marketable securities with an original maturity of greater than 90 days. The Company has designated all investments as available-for-sale and therefore, such investments are reported at fair value. For securities sold prior to maturity, the cost of securities sold is based on the specific identification method. Realized gains and losses on the sale of investments are recorded in interest income (expense), net. Interest is recorded when earned. Investments with original maturities greater than approximately three months and remaining maturities less than one year are classified as short-term investments. Investments with remaining maturities greater than one year are classified as long-term investments. The Company considers securities with maturities of three months or less from the purchase date to be cash equivalents.

At December 31, 2016, the aggregate fair value of the Company's marketable securities was $11,577. At December 31, 2015, the aggregate fair value of the Company's marketable securities was $5,274. Gross unrealized gains and losses were insignificant for the years ended December 31, 2016 and 2015.

We conduct periodic reviews to identify and evaluate each investment that is in an unrealized loss position in order to determine whether an other-than-temporary impairment exists. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. Unrealized losses on available-for-sale debt securities that are determined to be temporary, and not related to credit loss, are recorded, net of tax, in accumulated other comprehensive income (loss).

Table of Contents

Restricted cash

Restricted cash as of December 31, 2016 and 2015 was $361 and included a $50 security deposit related to the Company's credit card account and 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 sheets for cash, cash equivalents, marketable securities and accounts payable approximate fair value based on the short term nature of these instruments. The carrying value of the loan payable approximates fair value due to market terms.

Property and equipment

Property and equipment are carried at cost. Depreciation and amortization expense are recorded 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

Research and development expenses

Costs incurred for research and development are expensed as incurred.

Concentrations of credit risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents, and marketable securities. The Company maintains cash in commercial banks, which may at times exceed Federally Insured limits. The Company has not experienced any loss in such accounts. The Company believes it is not exposed to any significant credit risk on cash and cash equivalents.

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, 2016 and 2015, all of the Company's assets were located in one location in the United States.

Income taxes

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

Tax positions not deemed to meet a more likely than not threshold would be recorded as a tax expense in the current year. There were no material uncertain tax positions that required accrual or disclosure to the financial statements

Table of Contents

as of December 31, 2016 or 2015. Tax years subsequent to 2013 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, 2016, 2015, and 2014.

Share based payments

The Company accounts for all stock-based payment awards granted to employees and nonemployees using a fair value method. The Company's stock-based payments include stock options and grants of common stock, including common stock subject to vesting. The measurement date for employee awards is the date of grant, and stock-based compensation costs are recognized as expense over the employees' requisite service period, which is the vesting period, on a straight-line basis. The measurement date for nonemployee awards is the date the services are completed, resulting in periodic adjustments to stock-based compensation during the vesting period for changes in the fair value of the awards. Stock-based compensation costs for nonemployees are recognized as expense over the vesting period on a straight-line basis. Stock-based compensation is classified in the accompanying consolidated statements of operations and comprehensive loss based on the department to which the related services are provided.

Derivative instruments

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

Net loss per common share

Basic net loss per share of common stock has been computed by dividing net 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 related to the Company's May 2014 capital raise, which include an anti-dilution provisions, and convertible securities are anti dilutive and therefore excluded from diluted loss per share calculations.

For the year ended December 31, 2016, 2015, and 2014, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive:

	2016	2015	2014
Stock options	3,193,785	3,253,310	2,606,737
Warrants	3,391,439	1,156,779	10,208,849
	6,585,224	4,410,089	12,815,586

Table of Contents

Reclassifications

Certain amounts in prior period financial statements have been reclassified to conform to the current period presentation. Marketable securities were previously included in cash and cash equivalents on the balance sheet but are now reflected as a separate line item on the balance sheet. Cash activities related to the purchase and sale of marketable securities have been reflected within investing activities in the statement of cash flows. The unrealized gains or losses related to these marketable securities are immaterial for all periods presented.

Recent accounting pronouncements

In August 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-15, Presentation of Financial Statements—Going Concern, on disclosure of uncertainties about an entity's ability to continue as a going concern. This guidance addresses management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosures. The guidance is effective for fiscal years ending after December 15, 2016 including interim reporting periods within each annual reporting period, with early adoption permitted. The Company adopted this guidance as of December 31, 2016. The adoption of ASU 2014-15 impacted presentation and disclosure only and did not have any impact on the Company’s financial position or results of operations.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (“ASU 2014-09”) to provide updated guidance on revenue recognition. ASU 2014-09 requires a company to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies may need to use more judgment and make more estimates than under today’s guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price, and allocating the transaction price to each separate performance obligation. In August 2015, the FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which deferred the effective date of ASU 2014-09 by one year. Accordingly, ASU 2014-09 is effective for public business entities for annual reporting periods beginning after December 15, 2017, including interim reporting periods within each annual reporting period. In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross Versus Net), which clarifies the implementation guidance on principal versus agent considerations. In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients, which relates to disclosures of remaining performance obligations, as well as other amendments to guidance on collectability, non-cash consideration and the presentation of sales and other similar taxes collected from

customers. These standards have the same effective date and transition date of December 15, 2017. Currently, this guidance is not applicable to the Company as the Company is still in the research and development stage. However, the Company will continue to evaluate the impact of adopting ASU 2014-09 on its consolidated financial statements when the Company begins to generate revenue.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The guidance in this ASU supersedes the leasing guidance in Topic 840, Leases. Under the new guidance, lessees are required to recognize lease assets and lease liabilities on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance leases or operating leases, with classification affecting the pattern of expense recognition in the statement of operations. The new standard is effective for annual reporting periods beginning after December 15, 2018, including interim reporting periods within each annual reporting period. The Company is currently evaluating the impact of the adoption of this ASU on the financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Accounting (“ASU 2016-09”) to require changes to several areas of employee share-based payment accounting in an effort to simplify share-based reporting. The update revises requirements in the following areas: minimum statutory withholding, accounting for income taxes, forfeitures, and intrinsic value accounting for private entities. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016, including

Table of Contents

interim reporting periods within each annual reporting period. The Company will adopt this standard on January 1, 2017, and the adoption is not expected to have a material impact on the Company's financial statements.

In August 2016, the FASB issued ASU No. 2016-15, Classification of Certain Cash Receipts and Cash Payments ("ASU 2016-15") to address how certain cash receipts and cash payments are presented and classified in the statement of cash flows in an effort to reduce existing diversity in practice. The update includes eight specific cash flow issues and provides guidance on the appropriate cash flow presentation for each. ASU 2016-15 is effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within each annual reporting period. The Company does not expect the adoption of this guidance to have a material impact on the financial statements.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash to clarify how entities should present restricted cash and restricted cash equivalents in the statement of cash flows. Under this new update, entities are required to show the changes in the total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. This guidance will be applied retrospectively and is effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within each annual reporting period. The Company is currently evaluating the impact of the adoption of this ASU on the financial statements.

3. MARKETABLE SECURITIES

The Company invests its excess cash in fixed income instruments denominated and payable in U.S. dollars including money market accounts, commercial paper, and corporate obligations in accordance with the Company's investment policy that primarily seeks to maintain adequate liquidity and preserve capital.

The following table summarizes the Company's cash, cash equivalents, and marketable securities as of December 31, 2016 and 2015:

	December 31,	
	2016	2015
Cash	$ 111	$ 116
Money market funds	21,353	14,804
Marketable securities	11,577	5,274
Total cash, cash equivalents and marketable securities	$ 33,041	$ 20,194

As of December 31, 2016, the Company's investment portfolio consists of marketable securities with an original maturity of greater than 90 days. The Company has designated all investments as available-for-sale and therefore, such investments are reported at fair value. As of December 31, 2016, the fair value of the Company's marketable securities approximates amortized cost and therefore the insignificant gains/losses on these securities have been included within Other Income (Expense) on the Statement of Operations.

The following table summarizes the Company's short-term investments in marketable securities by category as of December 31, 2016 and 2015:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
December 31, 2016				
Commercial paper	4,240			4,240
Corporate obligations	7,337	—	—	7,337
Total	$ 11,577	$ —	$ —	$ 11,577
December 31, 2015				
Commercial paper	349			349
Corporate obligations	4,925	—	—	4,925
Total	$ 5,274	$ —	$ —	$ 5,274

As of December 31, 2016 and 2015, the Company's investments in marketable securities are classified in current assets as they are due in one year or less.

Table of Contents

4. PROPERTY AND EQUIPMENT

Property and equipment, net consisted of the following:

	2016	2015
Computer software and hardware	$ 606	$ 562
Research and lab equipment	1,895	1,874
Leasehold improvements	431	392
Office equipment	796	792
Less accumulated depreciation and amortization	(3,218)	(2,682)
Property and equipment, net	$ 510	$ 938

Depreciation and amortization expense for the years ended December 31, 2016, 2015, and 2014 was $536, $672, and $735, respectively. Maintenance and repairs are charged to expense as incurred and any additions or improvements are capitalized. The Company had no disposals for the years ended December 31, 2016 and 2015.

5. 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.

	2016	2015
Patent licensing fee	$ 200	$ 200
Accumulated amortization	(122)	(104)
	$ 78	$ 96

For each of the years ended December 31, 2016, 2015, and 2014, the amortization expense was $17. Amortization expense is expected to be $17 per year for 2017, 2018, 2019, and 2020, and $10 in 2021.

6. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	December 31,	
	2016	2015
Accrued bonus	$ 906	$ —
Accrued payroll	126	85
Accrued vacation	91	81
Accrued severance	385	—
Other accrued expenses	451	208
Total accrued expenses	$ 1,959	$ 374

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.

Table of Contents

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 the 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, 2016			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	$ 21,353	$ —	$ —	$ 21,353
Marketable securities	—	11,577	—	11,577
Derivative warrant liability	$ —	$ 1,314	$ —	$ 1,314

	At December 31, 2015			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	$ 14,804	$ —	$ —	$ 14,804
Marketable securities	—	5,274	—	5,274
Derivative warrant liability	$ —	$ 1,907	$ —	$ 1,907

8. 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%. This non-cancelable purchase agreement was still in effect at December 31, 2016, but there are no future minimum principal payments to be made under the agreement due to the fact that any amounts due have been paid in full. 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.

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 designated to be used for working capital purposes and the remainder to be used for the purchase of capital equipment. The annual interest rate on the loan 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, until the final maturity of the loan on October 5, 2019. Commencing on May 1, 2015, equal monthly principal payments of $41 are due until loan maturity. Therefore, for the years ending December 31, 2017, 2018, and 2019, principal payments of $423, $452, and $400, respectively, will be due. In October 2012, as part of the agreement, the Company issued MassDev a warrant for the purchase of 9,037 shares of the Company's common stock. The warrant has a seven-year term and is exercisable at $6.64 per share. The fair value of the warrant was determined to be $32 and is being amortized through interest expense over the life of the note. For each of the years ended December 31, 2016, 2015, and 2014, amortization expense 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. Interest expense related to this loan was $99, $126, and $127 for the years ended December 31, 2016, 2015, and 2014, respectively.

Table of Contents

At December 31, loans payable consisted of the following:

	December 31,	
	2016	2015
MassDev Loan	$ 1,275	$ 1,670
Less: current portion	(423)	(395)
	$ 852	$ 1,275

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, 2016, the Company had U.S. federal and Massachusetts net operating loss carryforwards of $95,872 and $88,041, respectively, of which federal carryforwards will expire in varying amounts beginning in 2026. Massachusetts net operating losses begin to expire in 2029. 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 has completed several financings since its inception, which may have resulted in a change in ownership, or could result in a change in ownership in the future, but has not yet completed an analysis of whether an ownership change limitation exists. The Company will complete an appropriate analysis before its tax attributes are utilized. The Company also had federal and state research and development tax credits of $944 and $183, respectively, at December 31, 2016, which will begin to expire in 2025 unless previously utilized.

Significant components of the Company’s net deferred tax assets are as follows:

	December 31,	
	2016	2015
Net operating loss carryforward	$ 37,245	$ 30,014
Research and development credit carryforward	1,065	942
Stock-based compensation	5,235	3,307
Depreciation and amortization	31	(48)
Accrued expenses	264	186
Charitable contributions	63	96

Subtotal	43,903	34,497
Valuation allowance	(43,903)	(34,497)
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, 2016 and 2015, the valuation allowance increased by $9,406 and $8,727, respectively.

The Company has no uncertain tax positions at December 31, 2016 and 2015 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.

Table of Contents

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

	December 31,		
	2016	2015	2014
Statutory rate	(34.0)%	(34.0)%	(34.0)%
State taxes, net of benefit	(5.4) %	(3.5) %	(4.8) %
Permanent differences:			
Derivative losses	(0.9) %	11.0 %	0.7 %
Other	0.2 %	0.3 %	2.6 %
R&D tax credit	(0.5) %	(0.4) %	(1.0) %
Other	0.5 %	0.4 %	2.2 %
Increase in valuation reserve	40.1 %	26.2 %	34.3 %
Effective tax rate	0.0 %	0.0 %	0.0 %

11. COMMON STOCK

The Company has authorized 100,000,000 shares of common stock, $0.00001 par value per share, of which 32,044,087, shares were issued and outstanding as of December 31, 2016 and 27,555,948 shares were issued and outstanding as of December 31, 2015.

During the year ended December 31, 2016, the Company issued an aggregate of 135,205 shares of common stock upon the exercise of stock options and received cash proceeds from such exercises of $191.

During the year ended December 31, 2016, the Company issued an aggregate of 4,979 shares of common stock upon the cashless exercise of warrants.

During the year ended December 31, 2016, the Company issued an aggregate of 37,528 shares of common stock with a fair value of $208 to the Company's 401(k) plan as a matching contribution.

During the year ended December 31, 2016, the Company issued an aggregate of 16,729 shares of common stock under the Company's Employee Stock Purchase Plan (the "ESPP") and received cash proceeds of $91.

In March 2016, the Company closed an underwritten public offering of an aggregate of 4,293,333 shares of common stock and warrants to purchase an aggregate of 2,146,666 shares of common stock, at a price to the public of $7.49 per share of common stock and $0.01 per warrant. The net proceeds to the Company, after deducting underwriting discounts and offering expenses, were approximately $29,905. The warrants have a per share exercise price of $10.00, or approximately 133% of the public offering price of the common stock, are exercisable immediately, and expire on March 18, 2021. The warrants contain a cashless exercise feature whereby shares are withheld to cover the exercise cost and the warrant holder receives a net issuance of the remaining shares. The Company intends to use the net proceeds from the offering to fund ongoing clinical trials and for general corporate purposes.

During the year ended December 31, 2015, the Company issued an aggregate of 316,177 shares of common stock upon the exercise of stock options, including stock options to purchase 52,224 shares of common stock exercised through cashless exercise provisions resulting in the issuance of 14,961 shares of common stock and stock options to purchase 301,216 shares of common stock exercised for cash, providing cash proceeds of $1,068.

During the year ended December 31, 2015, the Company issued an aggregate of 1,379,575 shares of common stock upon the exercise of warrants, including warrants to purchase 40,955 shares of common stock exercised through cashless exercise provisions resulting in the issuance of 25,052 shares of common stock and warrants to purchase

1,354,523 shares of common stock exercised for cash, providing net cash proceeds of $7,789.

During the year ended December 31, 2015, the Company issued an aggregate of 17,437 shares of common stock with a fair value of $201 to the Company’s 401(k) plan as a matching contribution.

Table of Contents

In January 2015, the Company closed a registered direct offering of an aggregate of 2,000,000 shares of common stock, resulting in net proceeds of $11,038.

As part of the adjustment to reflect the Company's 1-for-4 reverse stock split on its common stock on April 8, 2015, the Company issued 1,514 shares of common stock to account for the fractional roundup of shareholders.

In July 2015, the Company entered into a Sales Agreement (the "Sales Agreement") with Cowen and Company, LLC ("Cowen") pursuant to which the Company may issue and sell from time to time shares of common stock having aggregate sales proceeds of up to $50 million through an "at the market" equity offering program under which Cowen acts as the Company's sales agent. The Company is required to pay Cowen a commission of 3% on the gross proceeds from the sale of shares of common stock under the Sales Agreement. The Company issued 388,245 shares of common stock under the Sales Agreement during the year ended December 31, 2015, providing cash proceeds of $3,442, net, through this facility.

During the year ended December 31, 2014, the Company issued an aggregate of 132,900 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 9,975 shares of common stock upon the exercise of warrants, including warrants to purchase 15,655 shares of common stock exercised through cashless exercise provisions resulting in the issuance of 6,903 shares of common stock and warrants to purchase 3,072 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 41,753 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 27,212 and 5,594 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 41,821 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.

During the year ended December 31, 2014, the Company closed an underwritten public offering of an aggregate of 3,500,312 shares of common stock and warrants to purchase up to an aggregate of 1,750,156 shares of common stock, at a price to the public of $4.60 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 $5.75, or 125% of the public offering of the common stock, and expire on May 9, 2019.

Common Stock Reserves

As of December 31, 2016, the Company had the following reserves established for the future issuance of common stock as follows:

Reserves for the exercise of warrants	3,391,439
Reserves for the exercise of stock options	3,193,785
Total Reserves	6,585,224

12. DERIVATIVE INSTRUMENTS

The warrants issued in connection with the Company's May 2014 public offering to purchase 1,750,156 shares of the common stock (see Note 11) have anti-dilution protection provisions and, under certain conditions, require the Company to automatically reprice the warrants. Accordingly, these warrants are accounted for as derivative warrant liabilities. The Company used the Binomial Lattice 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 the fair value of the derivative financial instruments are recognized currently in the Company's consolidated statement of operations as a derivative gain or loss. The warrant derivative gains or losses are non-cash expenses and for the years ended December 31, 2016,

Table of Contents

2015, and 2014, a (gain) loss of $(593), $10,804 and $376, respectively, were included in other income (expense) in the Company's consolidated statement of operations.

The fair value of these derivative instruments at December 31, 2016 and 2015 was $1,314 and $1,907, respectively, and was included as a derivative warrant liability in current liabilities. The assumptions used principally in determining the fair value of warrants were as follows:

	Year Ended December 31,					
	2016		2015		2014	
Risk-free interest rate	1.20	%	0.65	%	1.47	%
Expected dividend yield	0	%	0	%	0	%
Contractual term	2.4	years	3.4	years	4.4	years
Expected volatility	89	%	100	%	119	%

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, 2016, 2015, and 2014:

	Year Ended December 31,		
	2016	2015	2014
Balance at beginning of year	$ 1,907	$ 7,224	$ —
Issuance of warrants	—	—	6,848
(Decrease) increase in the fair value of the warrants	(593)	10,804	376
Fair value of derivative warrant liability reclassified to additional paid in capital	—	(16,121)	—
Balance at end of year	$ 1,314	$ 1,907	$ 7,224

ty

13. STOCK OPTIONS

In 2007, the Company's Board of Directors adopted, and the Company's shareholders subsequently approved, 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, 2016, there were options to purchase an aggregate of 150,207 shares of common stock outstanding under the 2007 Plan and no shares available for future grants under the 2007 Plan.

On October 26, 2010, the Company's Board of Directors adopted, and the Company's shareholders subsequently approved, the 2010 Equity Incentive Plan (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.

In April 2015, the Company's Board of Directors adopted, and the Company' shareholders subsequently approved, the 2015 Equity Incentive Plan (the "2015 Plan"). The 2015 Plan provides for grants of incentive stock options to employees, and nonqualified stock, restricted common stock, restricted stock units and stock appreciation rights to employees, consultants, and directors of the Company.

As of December 31, 2016, the total number of shares authorized for issuance under the 2015 Plan was 4,322,355 shares, consisting of 4,000,000 shares initially approved under the 2015 Plan plus the 322,355 shares that remained available for grant under the 2010 Plan at the time of its termination. Upon approval of the 2015 Plan by the Company's shareholders on June 16, 2016, the 2010 Plan was terminated and no additional shares or share awards have been subsequently granted under the 2010 Plan.

As of December 31, 2016, there were outstanding options to purchase an aggregate of 1,222,085 and 1,821,487 shares of common stock under the 2015 Plan and 2010 Plan, respectively. Options issued under the Plans are exercisable for up to 10 years from the date of issuance.

Table of Contents

Options issued under the 2007 Plan, 2010 Plan, and 2015 Plan (collectively, the “Plans”) are exercisable for up to 10 years from the date of issuance.

In March 2015, the Company’s Board of Directors adopted, and the Company’s shareholders subsequently approved the ESPP. The ESPP allows employees to buy company stock twice a year through after-tax payroll deductions at a discount from market. The Company’s Board of Directors initially authorized 187,500 shares for issuance under the ESPP. Commencing on the first day of the year ended December 31, 2016 and on the first day of each year thereafter during the term of the ESPP, the number of shares of common stock reserved for issuance shall be increased by the lesser of (i) 1% of the Company’s outstanding shares of common stock on such date, (ii) 50,000 shares or (iii) a lesser amount determined by the Board of Directors. Under the terms of the ESPP, in no event shall the aggregate number of shares reserved for issuance during the term of the ESPP exceed 1,250,000 shares.

The 2015 ESPP is considered a compensatory plan with the related compensation cost recognized over each respective six month offering period. As of December 31, 2016, approximately $51 of employee payroll deductions had been withheld since July 1, 2016, the commencement of the offering period, and are included in accrued expenses in the accompanying balance sheet. The compensation expense related to the ESPP for the years ended December 31, 2016 and 2015 was $46 and $41, respectively, and is included in stock-based compensation expense. In January 2017, 7,986 shares that were purchased as of December 31, 2016 were issued under the ESPP.

Share based compensation

For the years ended December 31, 2016, 2015 and 2014, the Company recorded stock based compensation expense of $5,063, $4,666, and $2,730, respectively, net of forfeitures, inclusive of the expense related to the ESPP.

The fair value of each option award is estimated on the date of grant using the Black Scholes option pricing model, which uses the assumptions noted in the following table. 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, 2016	2015	2014
Risk-free interest rate	1.20 - 1.52%	1.53 - 1.89%	1.62 - 2.06%
Expected dividend yield	0%	0%	0%
Expected term (employee grants)	5.99 years	6.00 years	6.03 years
Expected volatility	111%	116%	124%

A summary of option activity as of December 31, 2016 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, 2015	3,253,310	$ 7.47		
Granted	333,250	$ 6.27		
Forfeited	(257,570)	$ 8.47		
Exercised	(135,205)	$ 1.41		
Outstanding at December 31, 2016	3,193,785	$ 7.52	6.93	$ 571
Vested at December 31, 2016	1,811,996	$ 7.54	6.32	$ 563
Vested and expected to vest at December 31, 2016	2,741,045	$ 7.52	6.81	$ 568

The weighted average grant date fair value of options granted during the years ended December 31, 2016, 2015,

Table of Contents

and 2014 was $5.23, $7.37, and $6.15 per share, respectively. The total fair value of options that vested in the years ended December 31, 2016, 2015, and 2014 was $5,179, $5,144, and $2,329, respectively. As of December 31, 2016, there was $5,630 of total unrecognized compensation expense related to non vested share based option compensation arrangements. The unrecognized compensation expense is estimated to be recognized over a period of 2.37 years at December 31, 2016.

14. WARRANTS

The following table presents information about warrants to purchase common stock issued and outstanding at December 31, 2016:

Year Issued	Classification	Number of Warrants	Exercise Price	Date of Expiration
2010	Equity	343,931	$ 5.60	10/26/2017 - 12/3/2017
2010	Equity	306,838	$ 4.00	8/30/2017 - 12/3/2017
2012	Equity	6,054	$ 6.64	10/5/2019
2014	Liability	587,950	$ 3.87	5/9/2019
2016	Equity	2,146,666	$ 10.00	3/18/2021
Total		3,391,439		
Weighted average exercise price			$ 7.94	
Weighted average life in years				3.24

In March 2016, the Company closed an underwritten public offering of an aggregate of 4,293,333 shares of common stock and warrants to purchase an aggregate of 2,146,666 shares of common stock, at a price to the public of $7.49 per share of common stock and $0.01 per warrant. The net proceeds to the Company, after deducting underwriting discounts and offering expenses, were approximately $29,905. The warrants have a per share exercise price of $10.00, or approximately 133% of the public offering price of the common stock, are exercisable immediately, and expire on March 18, 2021. The warrants are immediately exercisable, at the option of each holder, in whole or in part, in cash (except in the case of a cashless exercise as discussed below). The exercise price and number of shares of common stock issuable upon exercise of the warrants will be subject to adjustment in the event of any stock split, reverse stock split, stock dividend, recapitalization, or similar transaction, among other events as described in the warrants. In the event that shares of common stock underlying the warrants are no longer registered under the Securities Exchange Act of 1934, as amended, the holder may, in its sole discretion, exercise the warrant in whole or in part and, in lieu of making cash payment, elect instead to receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant.

The fair value of the warrants was estimated at $11,726 using a Black-Scholes model with the following assumptions: expected volatility of 112.82%, risk free interest rate of 1.34%, expected life of five years and no dividends.

The Company assessed whether the warrants require accounting as derivatives. The Company determined that the warrants were (1) indexed to the Company’s own stock and (2) classified in stockholders’ equity in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 815, Derivatives and Hedging. As such, the Company has concluded the warrants meet the scope exception for determining whether the instruments require accounting as derivatives and should be classified in stockholders’ equity.

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, 2016, 2015, and 2014, the Company made matching contributions in the form of shares of the Company's common stock. For the years ended December 31, 2016, 2015, and 2014, the Company issued 37,528, 17,437, and 41,753 shares of its common stock, respectively, with related fair values of $208, $201, and $173, respectively, which were recorded as expense in the statement of operations.

Table of Contents

16. INTELLECTUAL PROPERTY LICENSE

In July 2007, the Company entered into a worldwide exclusive license (the "BCH License") for patents co-owned by Boston Children's Hospital ("BCH") and the Massachusetts Institute of Technology 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 thereunder, 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. License fees and milestone payments are capitalized and the gross total at December 31, 2016 and 2015 was $200 (see Note 5). Maintenance and royalty costs are expensed as incurred.

17. COMMITMENTS AND CONTINGENCIES

Leases

On November 30, 2011, the Company entered into a commercial lease for 26,150 square feet of office, laboratory and manufacturing space in Cambridge, Massachusetts (as amended on September 17, 2012, 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, 2016 and 2015, the amount of the deferred rent liability is $276 and $391, respectively, 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. Such costs are recorded as leasehold improvements, which are amortized to rent expense over the term of the Cambridge Lease. As of December 31, 2016 and 2015, such leasehold improvements totaled $143 and $185, net of accumulated depreciation.

Pursuant to the terms of the non cancelable lease agreements in effect at December 31, 2016, the future minimum rent commitments are as follows:

Year Ended December 31,	
2017	1,289
2018	1,088
Total	$ 2,377

Total rent expense for the years ended December 31, 2016, 2015, and 2014, including month to month leases, was $918, $1,123 and $1,148, respectively, net of sublease income of $230 for the year ended December 31, 2016.

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

On March 31, 2016, the Company entered into a short-term lease with CRISPR Therapeutics, as subtenant, to sub-lease 5,233 square feet of our Facility (the “Sublease”). The lease term was from April 1, 2016 through January 31, 2017. On March 31, 2016, the Company received $51 covering the first month’s rent and a security deposit under the terms of the Sublease. The funds received for the security deposit, $26, are classified as a component of accrued expenses in the financial statements. The Sublease was terminated on January 31, 2017.

Table of Contents

Compensation Commitment

The Company entered into a compensation arrangement with an executive during September 2016 which provides for a future cash payment by the Company to the executive based on the February 13, 2017 stock price of the

executive's former employer. The award is earned over a period of one year. Accordingly, the expense related to the compensation arrangement was approximately $89 for the three months and $101 for the twelve months ended December 31, 2016. The liability is included within accrued expenses on the balance sheet and was recorded at fair value on a recurring basis until the final payment was determined on February 13, 2017.

Lawsuits with Former Employee

In November 2013, the Company filed a lawsuit against Francis Reynolds, its 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, and corporate waste, and seeks monetary damages and an accounting. The lawsuit involves approximately $500,000 worth of personal and/or exorbitant expenses that the Company alleges Mr. Reynolds inappropriately caused it to pay while he was serving as the Company's Chief Executive Officer, Chief Financial Officer, President, and Chairman of the Company's Board of Directors. On December 6, 2013, Mr. Reynolds answered the complaint, and filed counterclaims against the Company and the Company's 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 related to Mr. Reynolds's allegations that the Company and the Company's Board of Directors 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 that he did not receive. On January 9, 2014, the Company, along with the directors named in the counterclaims, filed the Company's answer. Discovery has now been completed and the Company's motion for summary judgment on all counts of the complaint and Reynolds' opposition to the motion for summary judgment was filed with the court on March 3, 2017.

The Company intends to continue to defend itself against these claims and, to date, the Company has not recorded any provision for losses that may arise.

On July 22, 2016, Mr. Reynolds filed a lawsuit against the Company, certain present and former members of the Company's Board of Directors and an employee of the Company in Hillsborough County Superior Court, Southern District, Hillsborough County, New Hampshire (Reynolds v. InVivo Therapeutics Holdings Corp, et al.) alleging defamation, conspiracy, and tortious interference, and seeking monetary damages. In August 2016, the lawsuit was removed to the United States District Court for the District of New Hampshire. The Company filed a motion to dismiss this action and after oral argument on November 28, 2016, the Court on November 30, 2016 issued an order

dismissing the case for lack of personal jurisdiction. The judgment was entered on the docket on December 1, 2016, and the deadline for appealing that decision has passed.

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™ implant. The plaintiff sought 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 April 3, 2015, the United States District Court for the District of Massachusetts dismissed the plaintiff’s claim with prejudice.

On May 4, 2015, the plaintiff filed a notice of appeal of this decision. Following the submission of briefs by the parties, the Court of Appeals heard oral arguments on April 6, 2016. On January 9, 2017, the Court of Appeals for the First Circuit issued an order and opinion affirming the dismissal of the Securities Class Action with prejudice. Plaintiff has until April 10, 2017 to file a petition for certiorari to the United States Supreme Court.

Table of Contents

The Company intends to continue to defend itself against these claims and, to date, has not recorded any provision for losses that may arise.

On January 23, 2015, Shawn Luger, a purported shareholder of the Company, sent the Company a letter (the "Shareholder Demand") 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 Board of Directors completed its investigation of the matters raised in the Shareholder Demand and voted unanimously not to pursue any litigation against any current or former director, officer, or employee of the Company with respect to the matters set forth in the Shareholder Demand.

On August 14, 2015, Mr. Luger filed a shareholder derivative lawsuit in the Superior Court of Suffolk County for the Commonwealth of Massachusetts on behalf of the Company against certain present and former board members and company executives alleging the same breaches of fiduciary duties purportedly set forth in the Shareholder Demand. On February 5, 2016, the Superior Court of Suffolk County dismissed the plaintiff's claims with prejudice. On March 4, 2016, the plaintiff filed a notice of appeal of this decision. Following the submission of brief by the parties, the Appeals Court heard oral argument on December 13, 2016. On January 3, 2017, the Appeals Court issued an order and opinion affirming the dismissal of all claims with prejudice. The time period for Mr. Luger to appeal the Appeals Court's judgment has expired.

In addition, the Company received investigation subpoenas from the Boston Regional Office of the SEC and the Massachusetts Securities Division of the Secretary of the Commonwealth of Massachusetts ("MSD") requesting corporate documents concerning, among other topics, the allegations raised by the Securities Class Action and the Shareholder Demand. On October 21, 2015, after responding to the SEC's subpoena, the Company received a letter from the SEC notifying the Company that it had concluded its investigation of the Company and that it did not intend to recommend an enforcement action against the Company. The Company responded to the MSD's subpoena on September 22, 2014 and October 8, 2014. On February 18, 2015, the Company received a second subpoena from the MSD requesting additional documents and information related to the same topics. The Company responded to this second subpoena on March 24, 2015. The Company has not further heard from the MSD since it responded to this last subpoena.

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.

19. RELATED PARTY TRANSACTIONS

The Company has entered into a consulting agreement with Dr. Robert Langer, a member of the Company's Scientific Advisory Board and a holder of over 5% of the Company's common stock, for certain consulting services. Dr. Langer was one of the original co-founders of the Company. Pursuant to the terms of the agreement, the Company has agreed to pay Dr. Langer $250 per year in consulting fees.

20. SUBSEQUENT EVENTS

The Company has evaluated all events or transactions that occurred after December 31, 2016. In the judgment of management, there were no material events that impacted the consolidated financial statements or disclosures.

Table of Contents

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

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Our Disclosure Controls

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31. 2016. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the Securities and Exchange Commission (the “SEC”). Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of the Company’s disclosure controls and procedures as of December 31, 2016, the Company’s chief executive officer and chief financial officer concluded that, as of such date, the Company’s disclosure controls and procedures were effective at the reasonable assurance level.

Management’s Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) for the Company. 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, and includes those policies and procedures that:

· Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;

- 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

- 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 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, 2016 based on the framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 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, 2016.

Our registered public accounting firm has issued an attestation report on our internal control over financial reporting. This report appears on page 56 of this Annual Report on Form 10-K.

Table of Contents

Changes in Internal Control over Financial Reporting

During the fiscal quarter ended December 31, 2016, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

None.

Table of Contents

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 2017 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 2017 annual meeting of stockholders.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

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 2017 annual meeting of stockholders.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

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 2017 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 2017 annual meeting of stockholders.

Table of Contents

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.

Table of Contents

SIGNATURES

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

INVIVO THERAPEUTICS HOLDINGS CORP.

Date: March 10, 2017 By: /s/ MARK D. PERRIN
Name: Mark D. Perrin
Title: Chief Executive Officer (Principal Executive Officer)

Date: March 10, 2017 By: /s/ MELANIE GOLARZ
Name: Melanie Golarz
Title: Interim Chief Financial Officer (Principal Financial and Accounting 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 10, 2017
/s/ Melanie Golarz Melanie Golarz	Interim Chief Financial Officer (Principal Financial and Accounting Officer)	March 10, 2017
/s/ Christina Morrison Christina Morrison	Director	March 10, 2017
/s/ Kenneth DiPietro Kenneth DiPietro	Director	March 10, 2017

/s/ Daniel R. Marshak Daniel R. Marshak	Director	March 10, 2017
/s/ Jeffrey S. Hatfield Jeffrey S. Hatfield	Director	March 10, 2017
/s/ C. Ann Merrifield C. Ann Merrifield	Director	March 10, 2017
/s/ Richard J. Roberts Richard J. Roberts	Director	March 10, 2017

Table of Contents

EXHIBIT INDEX

2.1	Agreement and Plan of Merger, dated October 4, 2010, by and between Design Source, Inc. and InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 2.2 to the Company's Current Report on Form 8 K, as filed with the SEC on October 6, 2010).
2.2	Agreement and Plan of Merger and Reorganization, dated as of October 26, 2010, by and among InVivo Therapeutics Holdings Corp. (f/k/a Design Source, Inc.), a Nevada corporation, InVivo Therapeutics Acquisition Corp., a Delaware corporation and InVivo Therapeutics Corporation, a Delaware corporation (incorporated by reference from Exhibit 2.1 to the Company's Current Report on Form 8 K, as filed with the SEC on November 1, 2010).
3.1	Articles of Incorporation of InVivo Therapeutics Holdings Corp., as amended (incorporated by reference from Exhibit 3.1 to the Company's Quarterly Report on Form 10 Q for the quarter ended June 30, 2016, as filed with the SEC on August 4, 2016).
3.2	Amended and Restated Bylaws of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, as filed with the SEC on May 6, 2016).
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)
4.10	Form of Warrant Agreement (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on March 3, 2016).
10.1*	

		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).
10.2(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).

Table of Contents

10.2(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).
10.3*	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).
10.4(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).
10.4(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).
10.5	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).
10.6	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).
10.7	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).
10.8	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).
10.9	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).
10.10	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).
10.11	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).
10.12	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).
10.13*	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).
10.14	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).
10.15*	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).

10.16*	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).
10.17*	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).

Table of Contents

10.18*		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).
10.19*		Amendment to the December 31, 2013 Employment Agreement, dated as of April 29, 2014, between the Company and Steven F. McAllister (incorporated by reference from Exhibit 10.23 to the Company's Annual Report on Form 10 K for the fiscal year ended December 31, 2014, as filed with the SEC on March 11, 2015).
10.20*		Amended and Restated Employment Agreement, dated as of May 30, 2014, between the Company and Steven F. McAllister (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8 K, as filed with the SEC on May 30, 2014).
10.21*		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).
10.22		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).
10.23		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).
10.24*		InVivo Therapeutics Holdings Corp. Employee Stock Purchase Plan (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8 K, as filed with the SEC on June 16, 2015).
10.25*		InVivo Therapeutics Holdings Corp. 2015 Equity Incentive Plan (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8 K, as filed with the SEC on June 16, 2015).
10.26*		Letter Agreement regarding Amendments to Employment Agreement, dated as of July 21, 2015, by and between Mark D. Perrin and InVivo Therapeutics Holding Corp. (incorporated by reference from Exhibit 10.1 to the Company's Quarterly Report on Form 10 Q for the quarter ended September 30, 2015, as filed with the SEC on November 4, 2015).
10.27*		Letter Agreement regarding Amendments to Employment Agreement, dated as of July 21, 2015, by and between Steven F. McAllister and InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 10.2 to the Company's Quarterly Report on Form 10 Q for the quarter ended September 30, 2015, as filed with the SEC on November 4, 2015).
10.28*		Employment Agreement, dated July 21, 2015, by and between Thomas R. Ulich, M.D and InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 10.3 to the Company's Quarterly Report on Form 10 Q for the quarter ended September 30, 2015, as filed with the SEC on November 4, 2015).
10.29*		Employment Agreement, dated August 3, 2015, by and between Tamara L. Joseph and InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 10.4 to the Company's Quarterly Report on Form 10 Q for the quarter ended September 30, 2015, as filed with the SEC on November 4, 2015).
10.30*		Employment Agreement, dated August 10, 2016, by and between Pamela Stahl and InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, as filed with the SEC on November 4, 2016).
10.31*	+	Employment Agreement, dated January 31, 2015, and Letter Agreement regarding Amendments to such Employment Agreement, dated as of July 21, 2015, in each case by and between Lorianne Masuoka and InVivo Therapeutics Holdings Corp.
10.32*	+	Letter Agreement, dated October 6, 2016, by and between Lorianne Masuoka and InVivo Therapeutics Holdings Corp.
10.33	+	Consulting Agreement, dated January 3, 2017, by and between Lorianne Masuoka and InVivo Therapeutics Holdings Corp.
10.35		

	Exclusive License Agreement dated November 23, 2015 between InVivo Therapeutics Corporation and the University of California, San Diego
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 RSM US LLP
23.2	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.

Table of Contents

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.

+ Filed herewith.