INVIVO THERAPEUTICS HOLDINGS CORP.
Form 424B3
March 13, 2018
Table of Contents

Filed pursuant to Rule 424(b)(3)
Registration Statement No. 333-222738

PROSPECTUS SUPPLEMENT NO. 1

(TO PROSPECTUS DATED FEBRUARY 12, 2018)

INVIVO THERAPEUTICS HOLDINGS CORP.

Up to 10,700,000 shares of Common Stock

This prospectus supplement No. 1 supplements and amends the prospectus dated February 12, 2018 related to the sale or other disposition from time to time of up to 10,700,000 shares of common stock, par value $0.00001 per share, of InVivo Therapeutics Holdings Corp., a Nevada corporation (the “Company,” “we,” “us” or “our”), issued and issuable to Lincoln Park Capital Fund, LLC, the selling stockholder named in the prospectus, also referred to as Lincoln Park, pursuant to a purchase agreement dated January 25, 2018 that we entered into with Lincoln Park. We are not selling any shares of common stock under this prospectus and will not receive any of the proceeds from the sale of the shares of common stock by the selling stockholder.

This prospectus supplement should be read in conjunction with the prospectus dated February 12, 2018, which is to be delivered with this prospectus supplement. This prospectus supplement is qualified by reference to the prospectus except to the extent that the information in this prospectus supplement supersedes the information contained in the prospectus. This prospectus supplement is not complete without, and may not be delivered or utilized except in connection with, the prospectus, including any amendments or supplements to it.

Our common stock is currently quoted on The Nasdaq Global Market under the symbol “NVIV.” On March 12, 2018, the last reported sale price of our common stock on The Nasdaq Global Market was $0.67 per share.

This prospectus supplement incorporates into our prospectus the information contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the Securities and Exchange Commission on March 12, 2018 and attached hereto.

EXPERTS

The financial statements of InVivo Therapeutics Holdings Corp. as of December 31, 2017 and December 31, 2016 included in this prospectus supplement, have been so included in reliance on the audit report of RSM US LLP, an independent registered public accounting firm, given the authority of that firm as experts in accounting and auditing. The audit report of RSM US LLP included in this prospectus supplement includes an explanatory paragraph related to InVivo Therapeutics Holdings Corp. and its Subsidiary's ability to continue as a going concern.

Investing in our common stock involves risks. See "Risk Factors" beginning on page 8 of the prospectus.

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

The date of this prospectus supplement is March 13, 2018.

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, 2017
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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth 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
Emerging growth company			

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, 2017, the last business day of the registrant's most recently completed second fiscal quarter, was $86,007,844 based on a per share price of $2.70, which was the closing price of the registrant's common stock on the Nasdaq Global Market on such date.

As of March 9, 2018, the number of shares outstanding of the registrant's common stock, $0.00001 par value per share, was 38,054,036.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Table of Contents

INVIVO THERAPEUTICS HOLDINGS CORP.

ANNUAL REPORT ON FORM 10 K

FOR THE YEAR ENDED DECEMBER 31, 2017

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, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements include statements made regarding our commercialization strategy, future operations, cash requirements and liquidity, capital requirements, and other statements on our business plans and strategy, financial position, and market trends. In some cases, you can identify forward-looking statements by terms such as “may,” “might,” “will,” “should,” “believe,” “plan,” “intend,” “anticipate,” “target,” “estimate,” “expect,” and ot expressions. These forward-looking statements are subject to risks and uncertainties that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements in this Form 10-K, including factors such as our ability to raise substantial additional capital to finance our planned operations and to continue as a going concern; our ability to execute our strategy and business plan; our ability to obtain regulatory approvals for our products, including the Neuro-Spinal Scaffold™; our ability to successfully commercialize our current and future product candidates, including the Neuro-Spinal Scaffold; the progress and timing of our development programs; market acceptance of our products; our ability to retain management and other key personnel; our ability to promote, manufacture, and sell our products, either directly or through collaborative and other arrangements with third parties; and other factors detailed under “Risk Factors” in Part I, Item 1A of this Form 10-K. 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 initiate and complete the INSPIRE 2.0 Study to support our existing Humanitarian Device Exemption application;
- our ability to execute our strategy and business plan;
- our ability to obtain regulatory approvals for our current and future product candidates, including our Neuro-Spinal Scaffold implant;
- our ability to successfully commercialize our current and future product candidates, including our Neuro-Spinal Scaffold implant;

- the progress and timing of our current and future development programs;

- our ability to successfully open, enroll and complete clinical trials and obtain and maintain regulatory approval of our current and future 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 and adoption of our current and future technology and products;

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

- our ability to attract and retain key personnel.

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

Table of Contents

statements should be considered with any written or oral forward looking statements that we may issue in the future. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward looking statements to conform these statements to reflect actual results, later events or circumstances, or to reflect the occurrence of unanticipated events.

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

Item 1. BUSINESS

Overview

We are a research and clinical-stage biomaterials and biotechnology company with a focus on treatment of spinal cord injuries, or SCIs. Our mission is to redefine the life of the SCI patient, and we seek to develop 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. The Neuro-Spinal Scaffold implant incorporates intellectual property licensed under an exclusive, worldwide license from Boston Children’s Hospital and the Massachusetts Institute of Technology. We also plan to evaluate other technologies and therapeutics that may be complementary to our development of the Neuro-Spinal Scaffold implant or offer the potential to bring us closer to our goal of redefining the life of the SCI patient.

Market Opportunity

Our clinical program is intended to address the lack of successful treatments for SCIs, 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 285,000 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, or FDA, through the Humanitarian Device Exemption, or 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, or HUD, designation for the Neuro-Spinal Scaffold implant, 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, or 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 2017 by NSCISC titled “Spinal Cord Injury—Facts and Figures at a Glance”, (i) during the first year, average cost of care ranges from $352,279 to $1,079,412, depending on the severity of the injury, (ii) the net present value, or NPV, to maintain a quadriplegic injured at age 25 for life is $4,789,384, and (iii) the NPV to maintain a paraplegic injured at age 25 for life is $2,341,988. 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.

Table of Contents

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

We currently have one clinical development program for the treatment of acute SCI.

Neuro-Spinal Scaffold Implant for acute SCI

Our Neuro-Spinal Scaffold implant is an investigational bioresorbable polymer scaffold that is designed for implantation at the site of injury within a spinal cord. The Neuro-Spinal Scaffold implant 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 implant is composed of two biocompatible and bioresorbable polymers that are cast to form a highly porous investigational product:

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

· Poly-L-Lysine, a positively charged polymer commonly used to coat surfaces in order 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 implant by multiple combination strategies involving electrostimulation devices, additional biomaterials, drugs approved by the FDA, or growth factors. We expect the Neuro-Spinal Scaffold implant to be regulated by the FDA as a Class III medical device.

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

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.

Table of Contents

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, 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, or 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, or 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

Table of Contents

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 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, or 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 has been studied in 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, under an Investigational Device Exemption application for the treatment of neurologically complete thoracic traumatic acute SCI. We commenced an FDA-approved pilot study in 2014 that the FDA approved converting into The INSPIRE Study in January 2016. As of December 31, 2017, we had implanted our Neuro-Spinal Scaffold implant in a total of 19 patients in The INSPIRE Study, 16 of whom reached the six month primary endpoint visit, and three of whom died. In July 2017, after the third patient death, enrollment of patients in The INSPIRE Study was placed on hold as we engaged with the FDA to address the patient deaths. We subsequently closed enrollment in The INSPIRE Study and will follow the remaining active subjects until completion. Following discussions with the FDA, in March

2018, we received FDA approval for a randomized controlled trial to supplement the existing clinical evidence for the Neuro-Spinal Scaffold implant that we obtained from The INSPIRE Study. We refer to this herein as the INSPIRE 2.0 Study.

The purpose of The INSPIRE Study, which was the original study, was to evaluate whether the Neuro-Spinal Scaffold implant is safe and demonstrates probable benefit for the treatment of complete T2-T12 neurological level of injury (NLI) SCI. The primary endpoint was defined as the proportion of patients achieving an improvement of at least one AIS grade at six months' post-implantation. Additional endpoints included measurements of pain, sensory and motor scores, bladder and bowel function, Spinal Cord Independence Measure (a disability scale for patients with SCI), and quality of life. The INSPIRE Study included an Objective Performance Criterion, or 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. At the time enrollment of patients in The INSPIRE Study was placed on hold, the OPC was defined as 25% or more of the patients in the study demonstrating an improvement of at least one AIS grade at the six month post-implantation visit.

The FDA approved the enrollment of up to 30 patients in The INSPIRE Study so that there would be at least 20 evaluable patients at the primary endpoint analysis, accounting for events such as screen failures or deaths that would prevent a patient from reaching the primary endpoint visit. Of the 19 patients implanted in The INSPIRE Study, 16 patients have reached the six-month primary endpoint visit. Of these 16, seven had improved from complete AIS A SCI to incomplete SCI (two patients to AIS C and five patients to AIS B) at the six-month primary endpoint visit and nine had not demonstrated improvement at that visit. Three of the seven patients who improved were assessed to have AIS B SCI at the six-month primary endpoint and were later assessed to have improved to AIS C SCI at the 12 or 24-month

Table of Contents

visits. Two of the 16 patients were initially assessed to have improved from complete AIS A SCI to incomplete AIS B SCI, but each was later assessed to have reverted to complete AIS A SCI prior to the six-month examination. One of these two was then assessed at the six-month visit to have improved again to AIS B and the other remained AIS A. Since we have closed enrollment, the target of enrolling 20 evaluable patients into The INSPIRE Study will not be reached.

The FDA had previously recommended that we include a randomized, concurrent control arm in The INSPIRE Study. Acting on the FDA's recommendation, we proposed and received approval for the INSPIRE 2.0 Study (described below) to supplement the existing clinical evidence for the Neuro-Spinal Scaffold implant. In addition, as one source of comparator data, we initiated the Contemporary Thoracic SCI Registry Study, or the CONTEMPO Registry Study. The CONTEMPO Registry Study will utilize existing databases and registries to develop a historical comparator that, to the extent possible, matches patients to those patients enrolled in The INSPIRE Study. The CONTEMPO Registry Study is designed to provide comprehensive natural history benchmarks for The INSPIRE Study results that include SCI patients with similar baseline characteristics treated since 2006. The CONTEMPO Registry Study includes data from the Christopher & Dana Reeve Foundation North American Clinical Trials Network Registry, as well as the Model Systems Registry and the European Multicenter Study about Spinal Cord Injury. We anticipate that there will be between 100 to 200 patients in the CONTEMPO Registry Study. We have submitted a protocol for the CONTEMPO Registry Study to the FDA. We cannot be certain what additional information or studies will be required by the FDA to approve our HDE submission.

INSPIRE 2.0 Study

Our Neuro-Spinal Scaffold implant has been approved to be studied under our approved IDE in the INPSIRE 2.0 Study, which is titled the "Randomized, Controlled, Single-blind Study of Probable Benefit of the Neuro-Spinal Scaffold™ for Safety and Neurologic Recovery in Subjects with Complete Thoracic AIS A Spinal Cord Injury as Compared to Standard of Care." The purpose of the INSPIRE 2.0 Study is to assess the overall safety and probable benefit of the Neuro-Spinal Scaffold for the treatment of neurologically complete thoracic traumatic acute SCI. The INSPIRE 2.0 Study is designed enroll 10 subjects into each study arm, which we refer to as the Scaffold Arm and the Comparator Arm. Patients in the Comparator Arm will receive standard of care, which is spinal stabilization without dural opening or myelotomy. The INSPIRE 2.0 Study is a single blind study, meaning that the patients and assessors are blinded to treatment assignments. The FDA approved the enrollment of up to 35 patients in this study so that there would be at least 20 evaluable patients (10 in each study arm) at the primary endpoint analysis, accounting for events such as screen failures or deaths that would prevent a patient from reaching the primary endpoint visit. We may conduct the INSPIRE 2.0 Study at up to 26 sites in the United States. Enrolling patients in the INSPIRE 2.0 Study will also require the approval of the IRBs at each clinical site. We estimate that from study initiation, enrollment will take an approximately 18 months, and the total time to completion of the INSPIRE 2.0 study is estimated to be two years from study initiation.

The primary endpoint is defined as the proportion of patients achieving an improvement of at least one AIS grade at six months post-implantation. Assessments of AIS grade are at hospital discharge, three months, six months, 12 months and 24 months. The definition of study success for INSPIRE 2.0 is that the difference in the proportion of

subjects who demonstrate an improvement of at least one grade on AIS assessment at the six-month primary endpoint follow-up visit between the Scaffold Arm and the Comparator Arm must be equal to or greater than 20%. In one example, if 50% of subjects in the Scaffold Arm have an improvement of AIS grade at the six-month primary endpoint and 30% of subjects in the Comparator Arm have an improvement, then the difference in the proportion of subjects who demonstrated an improvement is equal to 20% (50% minus 30% equals 20%) and the definition of study success would be met. In another example, if 40% of subjects in the Scaffold Arm have an improvement of AIS grade at the six-month primary endpoint and 30% of subjects in the Comparator Arm have an improvement, then the difference in the proportion of subjects who demonstrated an improvement is equal to 10% (40% minus 30% equals 10%) and the definition of study success would not be met. Additional endpoints include measurements of changes in NLI, sensory levels and motor scores, bladder, bowel and sexual function, pain, Spinal Cord Independence Measure (a disability scale for patients with SCI), and quality of life.

We received approval for the INSPIRE 2.0 Study in early March. We believe this sets us in a direction towards a path to approval under the HDE regulatory program, and we are focused on exploring financing mechanisms to support the INSPIRE 2.0 Study.

Although The INSPIRE Study is structured with the OPC as the primary component for demonstrating probable

Table of Contents

benefit, the OPC is not the only variable that the FDA would evaluate when reviewing a future HDE application. Similarly, while our planned INSPIRE 2.0 Study is structured with a definition of study success requiring a minimum difference between study arms in the proportion of subjects achieving improvement, that success definition is not the only factor that the FDA would evaluate in the future HDE application. Approval is not guaranteed if the OPC is met for The INSPIRE Study or the definition of study success is met for the INSPIRE 2.0 Study, and even if the OPC or definition of study success are 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 2016, the FDA accepted our proposed HDE modular shell submission and review process for the Neuro-Spinal Scaffold implant. The HDE modular shell is comprised of three modules: a preclinical studies module, a 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 makes a filing decision that may trigger the review clock for an approval decision. We submitted the first module in March 2017 and received feedback in June 2017. We are working on responses to the FDA's questions and plan to submit an updated preclinical module in 2018. The HDE submission will not be complete until the manufacturing and clinical modules are also submitted.

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, or the BCH License. Issued patents and pending patent applications licensed under the BCH License cover the technology underlying our Neuro- Spinal Scaffold 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 issued United States patents and 16 issued international patents expiring between 2018 and 2027, and one pending United States patent application and seven pending international patent applications.

The BCH License has a term of 15 years from the effective date of July 2, 2007, 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

Table of Contents

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 implant. 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)").

Government Regulation

The testing, manufacturing, and potential labeling, advertising, promotion, distribution, import, and marketing of our products are and would be 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, or 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;
- 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, or 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;

Table of Contents

- 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, 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.

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.

Table of Contents

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, or 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 implant may meet the eligibility criteria to be sold for a profit.

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 or 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;

Table of Contents

- 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.

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 Scaffold Implant

We expect the Neuro-Spinal Scaffold implant 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

Table of Contents

than 4,000 patients per year at the time), 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 (the INSPIRE Study). Full approval of such conversion was subsequently granted in January 2016. In early March 2018, we received FDA approval for a randomized controlled trial (the INSPIRE 2.0 Study) to supplement the existing clinical evidence for the Neuro-Spinal Scaffold implant that we obtained from The INSPIRE Study.

In the future, if our Neuro-Spinal Scaffold implant 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 or 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 Conformity before drawing up a European Commission, or 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. We have not yet applied for a CE Mark for the Neuro-Spinal Scaffold implant.

If any of our products 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;

- 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, which is an organization designated by the competent authorities of an EEA country to conduct conformity assessments.

Further, the advertising and promotion of our products in the EEA is subject to regulatory directives concerning misleading and comparative advertising, and 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

Table of Contents

the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

Recent Development – Completion of strategic restructuring

In August 2017, we announced a strategic restructuring in order to focus on The INSPIRE Study. The strategic restructuring allowed us to concentrate efforts on defining a clinical path forward for the Neuro-Spinal Scaffold.

In conjunction with the strategic corporate restructuring, we completed a reduction in force eliminating approximately 39% of our workforce. See Note 17 in the accompanying notes to the condensed consolidated financial statements for additional information.

Financial Information and Research and Development Expenditures

We have incurred net losses each year since our inception, including net losses of $26.7 million for the year ended December 31, 2017, $23.4 million for the year ended December 31, 2016, and $33.3 million for the year ended December 31, 2015. 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 $11.1 million, $12.6 million and $10.1 million in 2017, 2016, and 2015, respectively.

Competition

We have many potential competitors, including major drug companies, specialized biotechnology firms, academic institutions, government agencies, and private and public research institutions. Many of these competitors have significantly greater financial and technical resources than us, and superior experience and expertise in research and development, preclinical testing, design and implementation of clinical trials, regulatory processes and obtaining regulatory approval for products, production and manufacturing, and sales and marketing of approved products. Smaller or early stage companies and research institutions may also prove to be significant competitors, particularly if they have collaborative arrangements with larger and more established biotechnology companies. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, and registering subjects for clinical trials.

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

Manufacturing

We have developed a proprietary manufacturing process to build our Neuro-Spinal Scaffold 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 2.0 Study. If we are able to 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

Table of Contents

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, 2017, 2016, and 2015, all of our assets were located in one location in the United States.

Employees

As of February 28, 2018, we had 12 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 financial, 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 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 we are continuing the existing business operations of InVivo Therapeutics Corporation as our wholly-owned subsidiary.

Our principal executive offices are located in leased premises at One Kendall Square, Suite B14402, Cambridge, Massachusetts 02139. Our telephone number is (617) 863-5500. We maintain a website at www.invivotherapeutics.com. Information contained on, or accessible through, our website is not a part of, and is not incorporated by reference into this 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.

Table of Contents

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

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. We may not be able to raise the funds to complete a clinical path, which may cause us to curtail or cease operations.

In July 2017, enrollment of patients in The INSPIRE Study of our Neuro-Spinal Scaffold implant was placed on hold following the third patient death in the trial, and we subsequently closed enrollment in The INSPIRE Study. Following our clinical trial hold in July 2017, we engaged in discussions with the FDA to define a clinical path forward. As part of the discussions with the FDA, we proposed, and FDA has approved, a randomized controlled trial to supplement the existing clinical evidence for the Neuro-Spinal Scaffold implant. We refer to this herein as the INSPIRE 2.0 Study. We cannot be certain that we will be able to raise the funds necessary for the clinical path forward.

Our financial statements as of December 31, 2017 were prepared under the assumption that we will continue as a going concern. At December 31, 2017, we had cash and cash equivalents of $12.9 million. We estimate that our existing cash resources will be sufficient to fund our operations into the fourth 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 current cash resources will not be sufficient to complete clinical development of our Neuro-Spinal Scaffold implant. If we are unable to raise capital, we may be forced to cease our operation entirely. Our ability to continue as a going concern will depend on our ability to obtain additional equity or debt financing, attain further operating efficiencies, reduce or contain 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 expressed substantial doubt as to our ability to continue as a going concern in its report dated March 12, 2018 included elsewhere in this Form 10-K.

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 will increase in connection with our ongoing activities, particularly if we undertake our planned INSPIRE 2.0 Study, and seek regulatory approval for our Neuro-Spinal Scaffold implant. In addition, if we obtain regulatory approval for any of our current or future 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.

Table of Contents

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 trials for our Neuro-Spinal Scaffold implant and any other product candidates that we may develop or acquire , including our planned INSPIRE 2.0 study;
- 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, 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 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.

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 $26.7 million for the year ended December 31, 2017 and $23.4 million for the year ended December 31, 2016. As of December 31, 2017, we had an accumulated deficit of $183.9 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

Table of Contents

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. 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.

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 clinical development of our Neuro-Spinal Scaffold implant;
- initiate or restart the research and development of 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 current and future 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.

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

Table of Contents

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, or NOLs, and research and development tax credits, or 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. Federal NOLs generated on or before December 31, 2017 can generally be carried back two years and carried forward for up to twenty years and can be applied to offset 100% of taxable income in such years. Under newly enacted federal income tax law, however, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, but may not be carried back and the deductibility of such federal NOLs is limited to 80% of taxable income in such years. It is uncertain how various states will respond to the newly enacted federal tax law.

In addition, 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, or 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.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Code. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the

deduction for NOLs to 80% of current year taxable income and elimination of NOL carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such NOLs may be carried forward indefinitely), one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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. We may also acquire the right to use certain intellectual property through licensing agreements, which could substantially increase our operating costs. Acquisitions and licensing agreements 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 or licensing agreement, it is likely we would issue equity securities as a significant 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 are wholly dependent on the success of one product candidate, the Neuro-Spinal Scaffold implant. Even if we are able to complete clinical development and 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 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 for our product candidate, 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.

The clinical trials of any of our current or future product candidates are, and the manufacturing and marketing of any such product candidates will be, subject to extensive and rigorous review and regulation by the FDA and other government authorities in the United States and in other countries where we intend to test and, if approved, market such product candidates.

We have experienced delays and may experience further delays in our clinical development of our Neuro-Spinal Scaffold implant. Clinical trials for future product candidates may also experience delays or may not be able to commence.

Before we can obtain regulatory approval for the sale of our Neuro-Spinal Scaffold implant, we must complete the clinical studies that are required. In July 2017, The INSPIRE Study of our Neuro-Spinal Scaffold implant was placed on hold following the third patient death in the trial. We subsequently closed enrollment in The INSPIRE Study and will follow the active patients until completion. We have proposed, and the FDA has approved the INSPIRE 2.0 Study. We may not be able to pursue the currently defined clinical path forward successfully, or in a timely manner or that is

Table of Contents

aligned with our cash resources. If we initiate the INSPIRE 2.0 Study to supplement the existing clinical evidence for the Neuro-Spinal Scaffold implant, it 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. Enrolling patients in any clinical trial of our Neuro-Spinal Scaffold implant will also require the approval of the IRBs at each clinical site.

In addition, our results may subsequently fail to meet the safety and probable benefit standards required to obtain regulatory approvals. For example, in The INSPIRE Study, two of the 16 evaluable patients were initially assessed to have improved from complete AIS A SCI to incomplete AIS B SCI, but each was later assessed to have reverted to complete AIS A SCI prior to the patient's six-month examination. Of these two patients, one patient had converted back to AIS B and the other remained at AIS A at the six-month examination. There is known and published variability in some of the measures used to assess AIS improvement and these measures can vary over time or depending upon the examiner. While we implemented procedures in The INSPIRE Study and will also implement procedures in any future clinical study, including the INSPIRE 2.0 Study, to limit such variations, we cannot be certain that regulatory authorities will accept the results of our clinical trials or interpret them the way that we do.

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, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtain 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 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 IRB 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 suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, a problematic 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 events, or changes in laws or regulations. In addition, regulatory agencies may require an audit with respect to the conduct of a clinical trial, which could cause further delays or increase costs. For example, in December 2017, we and several of our clinical sites and our CRO were subject to an FDA inspection in association with The INSPIRE Study. At the close of the inspection at InVivo, the FDA issued a Form 483 with two observations relating to our over oversight of clinical trial sites in The INSPIRE Study. We sought, and will continue to seek, input from the FDA regarding the scope and timing of our proposed remediation efforts and the FDA has indicated that our corrective actions appear adequate. We cannot be certain that we will not be subject to additional regulatory action by the FDA. We anticipate that our remediation efforts will add costs to our clinical development plans. Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and regulatory review process, and jeopardize our ability to obtain approval and commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Table of Contents

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;
- 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. In addition, in July 2017 we halted enrollment in the study, and subsequently closed enrollment in the study. We may experience similar delays with our planned INSPIRE 2.0 Study. 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 nonclinical studies and clinical 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 produce results to support regulatory approval. 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 development 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 events or unpleasant 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 ready for commercialization or achieve sales or profits.

Table of Contents

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 or additional 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 product candidates 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 implant. The HDE requires that there is no other comparable device available to provide therapy for a condition and requires 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. The amended protocol for The INSPIRE Study, which was approved in February 2016, established an 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. While we expect The INSPIRE Study to serve as one source of data used to support HDE approval in the future, we will not complete full enrollment of that study. In addition, although The INSPIRE Study is 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.

The FDA had previously recommended that we include a randomized, concurrent control arm in the study and we have proposed and received approval for the INSPIRE 2.0 Study. The primary endpoint is defined as the proportion of patients achieving an improvement of at least one AIS grade at six months post-implantation. The definition of study success is that the difference in the proportion of subjects who demonstrate an improvement of at least one grade on AIS assessment at the six-month primary endpoint follow-up visit between the Scaffold Arm and the Comparator Arm must be equal to or greater than 20%. While our planned INSPIRE 2.0 Study is structured with a definition of study success requiring a minimum difference between groups in the percentage of subjects achieving improvement, that success definition is not the only factor that the FDA would evaluate in the future HDE application.

Approval is not guaranteed if the OPC is met for The INSPIRE Study or the definition of study success is met for the INSPIRE 2.0 Study, and even if the OPC or definition of study success are 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 addition, as one source of comparator data, we initiated the CONTEMPO Registry Study, utilizing existing databases and registries to develop a historical comparator that, to the extent possible, matches patients to those patients enrolled in The INSPIRE Study. There can be no assurance that either our planned INSPIRE 2.0 Study or the CONTEMPO Registry Study will be successfully completed. Even if we successfully complete the INSPIRE 2.0 Study and the CONTEMPO Registry Study, we cannot be certain that the FDA will agree that these additional studies 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. Moreover, analysis of data from the CONTEMPO Registry Study may suggest a higher threshold for evidencing probable benefit. For example, preliminary data from certain registries we are using in the CONTEMPO Registry Study indicate that the conversion rate may be higher than the approximately 15.5% rate from the historical registries that were the basis for the selection of the current OPC for The INSPIRE Study. In the event our clinical data is not acceptable to the FDA, our ability to obtain approval under the HDE pathway may be delayed or may not be feasible. If the FDA does not approve our product candidates in a timely fashion, or at all, our business and financial condition will be adversely affected.

Table of Contents

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. With enactment of the FDA Reauthorization Act of 2017, Congress provided that the exemption for HUD / HDE profitability is available as long as the request for an exemption is submitted before October 1, 2022.

Some of our future products may be viewed by the FDA as combination products and the review of combination products is often more complex and more time consuming than the review of other types of products.

Our future products may be regulated by the FDA as combination products. For a combination product, the 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. The process of obtaining FDA marketing clearance or approval is lengthy, expensive, and uncertain, and we cannot be sure that any of our 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.

Table of Contents

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. 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.

26

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 product candidates, 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 FDA regulatory requirements, or if we experience unanticipated problems with any approved products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain regulatory approval, and the manufacturing processes, reporting requirements, post-approval clinical data, and promotional activities for such product, will be subject to continued regulatory review and oversight by the FDA. In particular, we and our third-party suppliers will be required to comply with the FDA's Quality System Regulations, or 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 and Good Tissue Practices with respect to any human cells and biologic products we may develop, and International Standards Organization 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
- criminal prosecution.

Table of Contents

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 impede our ability to carry on or expand our operations and could result in 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.

Further, even after we have obtained the proper regulatory clearance or approval to market a product, the FDA may 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 products, or the malfunction of our 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 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 decision 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 manufacture 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, 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. With the new Presidential administration and Congress, there have been, and may be additional, legislative changes affecting the Affordable Care Act, including repeal of certain provisions of the Affordable Care Act. It remains to be seen, however, precisely what impact legislation to date and any future legislation will have on the availability of healthcare and containing or reducing healthcare costs. 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. 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.

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 Scaffold 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.

Table of Contents

Risks Related to Our Intellectual Property

We license certain technology underlying the development of our Neuro-Spinal Scaffold implant 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 Boston Children's Hospital, or BCH, and the Massachusetts Institute of Technology, or 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.

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.

Table of Contents

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, 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.

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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. We have implemented restructurings that have significantly reduced our workforce over the last few months, leaving only key positions filled. On February 2, 2018, we appointed Richard Toselli M.D. as President, Chief Executive Officer, and a director. The loss of any members

Table of Contents

of senior management or key scientific personnel 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, and in the past have been, subject to lawsuits, which could divert management's attention and harm our business.

We are involved in litigation with our former Chairman, Chief Executive Officer, and Chief Financial Officer. We were previously the subject of a securities derivative lawsuit and a securities class action lawsuit, both of which were

dismissed in January 2017. We may face additional lawsuits, including class action or securities derivative lawsuits. The amount of time that is required to resolve these lawsuits is unpredictable and any lawsuits 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. See "Legal Proceedings" for further information regarding our litigation.

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.

Table of Contents

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;

- 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.

Table of Contents

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;

- 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.

If we fail to meet the requirements for continued listing on the Nasdaq Global Market, our common stock could be delisted from trading, which would decrease the liquidity of our common stock and our ability to raise additional capital.

Our common stock is currently listed for quotation on the Nasdaq Global Market. We are required to meet specified financial requirements in order to maintain our listing on the Nasdaq Global Market. One such requirement is that we maintain a minimum bid price of at least $1.00 per share for our common stock. On January 23, 2018 we

Table of Contents

received a deficiency letter from the Listings Qualifications Department of the Nasdaq Stock Market notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued inclusion on the Nasdaq Global Market, or the Bid Price Rule. We have been provided an initial period of 180 calendar days, or until July 23, 2018, or the Compliance Date, to regain compliance with the Bid Price Rule. If we do not regain compliance with the Bid Price Rule by the Compliance Date, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would need to transfer the listing of our common stock to the Nasdaq Capital Market, provided that we meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards of the Nasdaq Capital Market, with the exception of its bid price requirement, or, if we fail to meet its listing requirements, the OTC Bulletin Board. Any potential delisting of our common stock from the Nasdaq Global Market would make it more difficult for our stockholders to sell our stock in the public market and would likely result in decreased liquidity and increased volatility for our common stock.

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 publicly traded corporations, or Nevada corporations that elect to be subject to the law, and “interested stockholders” for two years after the interested stockholder first becomes an interested stockholder, unless the corporation’s board of directors approves the transaction by which the stockholder becomes an interested stockholder in advance, or the proposed combination in advance of the stockholder becoming an interested stockholder.

The proposed combination may be approved after the stockholder becomes an interested stockholder with preapproval by the board of directors and a vote at a special or annual meeting of stockholders holding at least 60% of the voting power not owned by the interested stockholder or his/her/ its affiliates or associates. After the two-year moratorium period, additional stockholder approvals or fair value requirements must be met by the interested shareholder up to four years after the stockholder became an interested stockholder. In addition, we may become subject to Nevada’s control share laws. A corporation is subject to Nevada’s control share law if it has more than 200 stockholders, at least 100 of whom are stockholders of record and residents of Nevada, and if the corporation does business in Nevada, including through an affiliated corporation. This control share law may have the effect of discouraging corporate takeovers. Currently, we believe that we have less than 100 stockholders of record who are residents of Nevada, and are therefore not subject to the control share laws.

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

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

We lease approximately 26,342 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 (the “Cambridge Lease”). On August 21, 2017, the Company exercised its option for the five-year extension on the Cambridge Lease. The five-year renewal lease term commences on November 1, 2018 and ends on October 31, 2023. We believe this facility is adequate to meet our current needs and that additional space could be available on commercially reasonable terms as needed.

On June 13, 2017, the Company entered into a short-term lease, as subtenant, to sublease 5,233 square feet of the facility. The lease term is from July 1, 2017 through October 26, 2018.

Table of Contents

We are in ongoing discussions to assign the Cambridge Lease, and sublease back a portion of the space thereunder for our manufacturing and quality functions. On February 16, 2018 the Company entered into a month to month membership agreement with WeWork to lease office space. This space will be used primarily for administrative functions.

Item 3. LEGAL PROCEEDINGS

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 relate to Mr. Reynolds's allegations that we and our 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 denying that Mr. Reynolds is entitled to any relief. The parties have completed discovery. On March 3, 2017, the counterclaim defendants filed a motion for summary judgement on all counterclaims asserted by Mr. Reynolds. On October 18, 2017, the Court allowed the motion for summary judgment in substantial part, and denied it in part. The Court, citing disputed issues of fact, declined to dismiss the counterclaims for breach of contract, breach of implied covenant of good faith and fair dealing, and declaratory judgment concerning Mr. Reynolds' attempted exercise of certain stock options, which Mr. Reynolds claims is the equivalent of 47,864 shares of common stock, but dismissed all other claims asserted by Mr. Reynolds. The trial is scheduled to begin on June 16, 2018.

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

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

Table of Contents

PART II

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

Market Information

Our common stock is 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 sales prices for our common stock for each full quarterly period in the two most recent fiscal years:

Fiscal Quarter Ended	High	Low
December 31, 2017	$ 2.25	0.72
September 30, 2017	$ 2.79	1.10
June 30, 2017	$ 4.30	1.90
March 31, 2017	$ 4.95	3.80

Fiscal Quarter Ended	High	Low
December 31, 2016	$ 6.77	$ 4.00
September 30, 2016	$ 7.94	$ 5.42
June 30, 2016	$ 7.10	$ 5.38
March 31, 2016	$ 10.36	$ 3.50

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 5, 2018, we had approximately 301 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.

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, 2012 through December 31, 2017. This graph assumes an investment of $100 on December 31, 2012 in our common stock and in each of the comparative indices and assumes reinvestment of dividends, if any.

Table of Contents

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, 2012 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

	2013	2014	2015	2016	2017
InVivo Therapeutics Holdings Corp	$ 131.95	$ 75.86	$ 103.45	$ 60.34	$ 11.06
NASDAQ Composite	$ 141.63	$ 162.09	$ 173.33	$ 187.19	$ 242.29
NASDAQ Biotechnology	$ 174.05	$ 230.33	$ 244.29	$ 194.95	$ 228.29

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)	2017	2016	2015	2014	2013
Operating expenses:					
Research and development	$ 11,083	$ 12,557	$ 10,058	$ 10,273	$ 10,533
General and administrative	13,510	11,506	12,340	7,566	8,472
Total operating expenses	24,593	24,063	22,398	17,839	19,005
Operating loss	(24,593)	(24,063)	(22,398)	(17,839)	(19,005)
Other income (expense):					
Interest income	189	187	60	5	15
Interest expense	(74)	(155)	(172)	(136)	(130)
Modification of warrants	—	—	—	—	(765)
Derivatives gain (loss)	(2,267)	593	(10,804)	(376)	(18,871)
Other income (expense), net	(2,152)	625	(10,916)	(507)	(19,751)
Net income (loss)	$ (26,745)	$ (23,438)	$ (33,314)	$ (18,346)	$ (38,756)
Net income (loss) per share, basic and diluted	$ (0.81)	$ (0.76)	$ (1.26)	$ (0.83)	$ (2.10)
Weighted average number of common shares outstanding, basic and diluted	32,950,068	31,025,585	26,461,374	22,080,761	18,497,922

	As of December 31,				
Condensed Consolidated Balance Sheet (in thousands)	2017	2016	2015	2014	2013

Cash, cash equivalents and marketable securities	$ 12,910	$ 33,041	$ 20,194	$ 13,459	$ 13,980
Working capital	10,694	29,005	17,427	6,169	12,334
Total assets	14,045	34,784	21,792	16,693	17,096
Long-term liabilities	823	987	1,551	1,991	1,938
Derivative warrant liability	4	1,314	1,907	7,224	—
Accumulated deficit	(183,907)	(157,007)	(133,569)	(100,255)	(81,909)
Stockholder's equity	10,110	28,949	16,929	5,918	12,890

We have derived our statements of operations data for the years ended December 31, 2014 and 2013 and our balance sheet data as of December 31, 2015, 2014, and 2013 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, 2017, 2016 and 2015 and our balance sheet data as of December 31, 2017 and 2016 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, 2017	September 30, 2017	June 30, 2017	March 31, 2017
Operating expenses:				
Research and development	$ 1,560	$ 2,928	$ 3,211	$ 3,384
General and administrative	3,122	3,388	3,715	3,285
Total operating expenses	4,682	6,316	6,926	6,669
Operating loss	(4,682)	(6,316)	(6,926)	(6,669)
Other income (expense):				
Interest income	37	43	52	57
Interest expense	(16)	(18)	(20)	(20)
Derivatives gain (loss)	(3)	(3,059)	554	241
Other income (expense), net	18	(3,034)	586	278
Net loss	$ (4,664)	$ (9,350)	$ (6,340)	$ (6,391)

	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)

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, or SCIs. Our mission is to redefine the life of the SCI patient, and we seek to develop 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. The Neuro-Spinal Scaffold implant incorporates intellectual property licensed under an exclusive, worldwide license from Boston Children's Hospital and the Massachusetts Institute of Technology. We also plan to evaluate other technologies and therapeutics

that may be complementary to our development of the Neuro-Spinal Scaffold implant or offer the potential to bring us closer to our goal of redefining the life of the SCI patient.

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. 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 12, “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 11, “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;

· expenses incurred under agreements with contract research organization (“CROs”), and clinical sites

Table of Contents

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.

Table of Contents

Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 interim reporting periods within each annual reporting period. We adopted this standard on January 1, 2017. Prior to adoption, we recognized share-based compensation, net of estimated forfeitures, over the vesting period of the grant. Upon adoption of ASU 2016-09, we elected to change our accounting policy to recognize forfeitures as they occur. We continue to recognize share-based compensation expense over the vesting period of the grant. The new forfeiture policy election was adopted using a modified retrospective approach with a cumulative effect adjustment of $155 recorded to accumulated deficit on the balance sheet as of January 1, 2017. Prior to January 1, 2017, we recognized the excess tax benefits of stock-based compensation expense as additional paid-in capital and tax deficiencies of stock-based compensation expense in the income tax provision or as additional paid-in capital to the extent that there were sufficient recognized excess tax benefits previously recognized. Previously, the excess tax benefits reduced taxes payable prior to being recognized as an increase in additional paid-in capital, and therefore we had not recognized certain deferred tax assets that could be attributed to tax deductions. As a result of the adoption, the deferred tax assets associated with certain net operating losses increased, which was offset by a corresponding increase in the valuation allowance and therefore the adoption of the tax-related guidance in this standard did not have an impact on our consolidated financial statements for the period ended December 31, 2017.

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 the 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 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. We do not expect the adoption of this guidance to have a material impact on the financial statements.

In May 2017, the FASB issued ASU No. 2017-09, Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting ("ASU 2017-09") to clarify when to account for a change to the terms or conditions of a share-based payment award as a modification. Under this new guidance, modification accounting is required if the fair value, vesting conditions, or classification of the award changes as a result of the change in terms or conditions. ASU 2017-09 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 the financial statements.

Table of Contents

In July 2017, the FASB issued ASU No. 2017-11, Part I. Accounting for Certain Financial Instruments with Down Round Features and Part II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11"). Part I of this guidance applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down round features. Part II of this guidance replaces the indefinite deferrals for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities. ASU 2017-11 is effective for annual reporting periods beginning after December 15, 2018, including interim reporting periods within each annual reporting period. We have concluded that the adoption of this ASU will not have a material impact on the financial statements.

In August 2017, the FASB issued ASU No. 2017-12, Derivatives and Hedging (Topic 815), which changes both the designation and measurement guidance for qualifying hedging relationships and the presentation of hedge results, in order to better align an entity's risk management activities and financial reporting for hedging relationships. The amendments expand and refine hedge accounting for both nonfinancial and financial risk components and align the recognition and presentation of the effects of the hedging instrument and the hedged item in the financial statements. FASB ASU No. 2017-12 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those annual reporting periods, with early adoption permitted. We are currently evaluating the impact of the adoption of this ASU on the financial statements.

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 are effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within each annual reporting period. Currently, this guidance is not applicable to us as we do not generate revenue. However, we will adopt the guidance and evaluate the impact of adopting ASU 2014-09 on the consolidated financial statements when we begin to generate revenue.

Results of Operations

Comparison of the Years Ended December 31, 2017 and 2016 (in thousands, except share and per share amounts)

Research and Development Expenses

Research and development expenses decreased by $1,474 to $11,083 for the year ended December 31, 2017 from $12,557 for the year ended December 31, 2016. This decrease is primarily attributable to a decrease in compensation related expenses of $1,629 largely as a result of the strategic restructuring in 2017, a decrease in contract services and laboratory supplies and intellectual property costs of $394 and $112 respectively as a result of our focused strategy, a decrease of $147 in facilities allocation charges partially offset by an increase of $715 in consulting and professional costs and an increase of $239 in clinical trial costs due to additional patient enrollment in The INSPIRE Study and the opening of additional clinical trial sites.

Table of Contents

General and Administrative Expenses

General and administrative expenses increased by $2,004 to $13,510 for the year ended December 31, 2017 from $11,506 for the year ended December 31, 2016. This increase in general and administrative expenses is attributable to increases in salaries related expenses including severance of $1,072, an increase of $492 in consulting and professional costs, an increase of $459 in facilities allocation charges and an increase of $376 in legal costs partially offset by a decrease in share-based compensation and recruiting expenses of $303 and $219 respectively.

Interest Income

Interest income remained relatively consistent at $189 for the year ended December 31, 2017 compared to $187 for the year ended December 31, 2016 due to comparable average investment balances in 2017 and 2016.

Interest Expense

Interest expense decreased by $81 to $74 for the year ended December 31, 2017 from $155 for the year ended December 31, 2016. This decrease in interest expense is due to lower average borrowings.

Derivatives Gain (Loss)

The derivatives loss for the year ended December 31, 2017 is $2,267 compared to a gain of $593 for the year ended December 31, 2016. The loss of $2,267 for the year ended December 31, 2017 can be attributed to the impact of the August 2017 warrant exchange and 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.

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, 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.

Table of Contents

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.

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, 2017, our accumulated deficit was $183,907.

At December 31, 2017, we had total assets of $14,045, total liabilities of $3,935, and total stockholders' equity of $10,110. We recorded a net loss of $26,745 for the year ended December 31, 2017. 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 an initial 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, 2017, our consolidated cash and cash equivalents balance was $12,910. We believe our current cash and cash equivalents are adequate to fund our operations into the fourth quarter of 2018.

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.

Table of Contents

On August 10, 2017, we entered into exchange agreements with certain holders of our warrants, dated May 9, 2014, to exchange such warrants for shares of common stock. We issued an aggregate of 2,021,419 shares of common stock to the warrant holders in exchange for their warrants to purchase an aggregate of 577,548 shares of common stock. The warrants exchanged in this transaction were subsequently cancelled and terminated. As a result of our issuance of common stock in exchange for certain of the warrants, the per share exercise price of the remaining warrants, dated May 9, 2014, was adjusted downwards from $3.87 per share to $0.83 per share and additional warrants were issued such that the remaining warrants were exercisable for an aggregate of 48,507 shares of common stock. We did not receive any cash proceeds from the warrant exchanges.

In the fourth quarter of 2017 and first quarter of 2018, we entered into warrant cancellation agreements with certain remaining holders of our warrants, dated May 9, 2014, to cancel and terminate such warrants for cash consideration. As of December 31, 2017, the remaining warrants were exercisable for an aggregate of 13,429 shares of common stock. The remaining warrants contain anti-dilution provisions that may be triggered by the future issuance by us of shares of our common stock or common stock equivalents at a price per share below the then-exercise price of the warrants, subject to some exceptions.

In January 2018, we entered into a purchase agreement and registration rights agreement with Lincoln Park Capital Fund, LLC (“Lincoln Park”). Pursuant to the terms of the purchase agreement, Lincoln Park agreed to purchase from us up to $15,000 of our common stock (subject to certain limitations) from time to time during the term of the purchase agreement. At the time we signed the purchase agreement and the registration rights agreement, we issued 429,800 shares of common stock (the “Commitment Shares”) to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the purchase agreement. As of March 12, 2018 the Company had drawn $2,252 against the purchase agreement and issued an aggregate of 3,344,769 shares exclusive of the commitment shares.

In August 2017, we announced a reduction in our workforce of approximately 39%. All affected employees received severance pay and outplacement assistance. As a result of the reduction in force and associated costs, we estimate savings of approximately $7.3 million in annual operating expenses, with one-time severance and related costs of $857. Of these one-time severance and related costs, approximately $509 was paid through December 31, 2017.

We may pursue various other dilutive and non dilutive funding alternatives depending upon our clinical path forward 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, 2017 was $19,683, the most significant drivers of which were our net loss of $26,745, offset by share-based compensation of $4,106 and derivative losses of $2,267.

Net cash from investing activities was $11,512 for the year ended December 31, 2017 attributable to the purchases of marketable securities of $8,256 and capital equipment of $65, offset by sales of marketable securities of $19,833.

Net cash used by financing activities was $383 for the year ended December 31, 2017 consisting of proceeds from the exercises of stock options, exercises of warrants, and Employee Stock Purchase Plan issuances of $80. These proceeds were offset by the repayment of loan principal of $423 and payment of $40 due to repurchase of warrants.

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.

Table of Contents

Contractual Obligations

The following summarizes our significant contractual obligations at December 31, 2017, 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	3-5 years	More than 5 years
Long term debt	$ 852	$ 452	$ 400	—	—
Operating lease payments	11,404	1,380	3,977	4,219	1,828
Total	$ 12,256	$ 1,832	$ 4,377	4,219	1,828

We are in ongoing discussions to assign the Cambridge Lease, and sublease back a portion of the space thereunder for our manufacturing and quality functions. If the Cambridge Lease assignment is successfully executed our operating lease payments will be materially reduced.

Commitments

See Note 16, “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 and cash equivalents of $12,910, or 92% of our total assets at December 31, 2017, and $33,041, or 95% of our total assets at December 31, 2016. Interest income earned on these assets was $189 in 2017 and $187 in 2016. Our interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates. At December 31, 2017, 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 Stockholders and the Board of Directors of

InVivo Therapeutics Holdings Corp. and Subsidiary

Cambridge, Massachusetts

Opinions on the Financial Statements and Internal Control Over Financial Reporting

We have audited the accompanying consolidated balance sheets of InVivo Therapeutics Holdings Corp. and Subsidiary (the Company) as of December 31, 2016 and 2017, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2017, and the related notes (collectively, the financial statements). We also have audited the Company’s internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013.

Emphasis of Matter

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

Basis for Opinions

The Company'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 the Company's financial statements and an opinion on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the financial statements included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. 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.

Table of Contents

Definition and Limitations of Internal Control Over Financial Reporting

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 (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 (3) 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.

/s/ RSM US LLP

We have served as the Company's auditor since 2015.

Boston, Massachusetts

March 12, 2018

Table of Contents

InVivo Therapeutics Holdings Corp.

Consolidated Balance Sheets

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

	December 31, 2017	2016
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 12,910	$ 21,464
Restricted cash	361	361
Marketable securities	—	11,577
Prepaid expenses and other current assets	535	451
Total current assets	13,806	33,853
Property, equipment and leasehold improvements, net	157	510
Other assets	82	421
Total assets	$ 14,045	$ 34,784
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 988	$ 1,011
Loan payable, current portion	452	423
Derivative warrant liability	4	1,314
Deferred rent, current portion	30	141
Accrued expenses	1,638	1,959
Total current liabilities	3,112	4,848
Loan payable, net of current portion	400	852
Deferred rent, net of current portion	367	135
Other liabilities	56	—
Total liabilities	3,935	5,835
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Common stock, $0.00001 par value, authorized 100,000,000 shares; 34,274,776 shares issued and outstanding at December 31, 2017; 32,044,087 shares issued and outstanding at December 31, 2016	1	1
Additional paid-in capital	194,016	185,955
Accumulated deficit	(183,907)	(157,007)
Total stockholders' equity	10,110	28,949
Total liabilities and stockholders' equity	$ 14,045	$ 34,784

See notes to the consolidated financial statements.

Table of Contents

InVivo Therapeutics Holdings Corp.

Consolidated Statements of Operations and Comprehensive Loss

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

	Year Ended December 31,		
	2017	2016	2015
Operating expenses:			
Research and development	$ 11,083	$ 12,557	$ 10,058
General and administrative	13,510	11,506	12,340
Total operating expenses	24,593	24,063	22,398
Operating loss	(24,593)	(24,063)	(22,398)
Other income (expense):			
Interest income	189	187	60
Interest expense	(74)	(155)	(172)
Derivatives gain (loss)	(2,267)	593	(10,804)
Other income (expense), net	(2,152)	625	(10,916)
Net loss	$ (26,745)	$ (23,438)	$ (33,314)
Net loss per share, basic and diluted	$ (0.81)	$ (0.76)	$ (1.26)
Weighted average number of common shares outstanding, basic and diluted	32,950,068	31,025,585	26,461,374
Other comprehensive loss:			
Net loss	$ (26,745)	$ (23,438)	$ (33,314)
Other comprehensive loss:			
Unrealized gain (loss) on marketable securities	—	—	—
Comprehensive loss	$ (26,745)	$ (23,438)	$ (33,314)

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, 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 offering	2,388,245	—	14,480	—	14,480
Issuance of common stock for services	—	—	—	—	—
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
Fractional shares issued due to reverse stock split	—	—	—	—	—
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
Cumulative adjustment on adoption of ASU 2016-09	—	—	155	(155)	—
Share-based compensation expense	—	—	4,106	—	4,106
Issuance of common stock on warrant exchange	2,021,419	—	3,537	—	3,537
Issuance of common stock for services	350	—	—	—	—
Issuance of common stock upon exercise of warrants	3,464	—	3	—	3
Issuance of common stock upon exercise of stock options	89,387	—	26	—	26
Issuance of common stock under ESPP	17,750	—	51	—	51
Issuance of common stock to 401(k) plan	98,319	—	183	—	183
Net loss	—	—	—	(26,745)	(26,745)
Balance as of December 31, 2017	34,274,776	$ 1	$ 194,016	$ (183,907)	$ 10,110

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,		
	2017	2016	2015
Cash flows from operating activities:			
Net loss	$ (26,745)	$ (23,438)	$ (33,314)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	395	548	684
Loss on impairment of fixed assets	41	—	—
Derivatives (gain) loss	2,267	(593)	10,804
Non-cash interest expense	5	5	5
Common stock issued to 401(k) plan	183	208	201
Share-based compensation expense	4,106	5,063	4,666
Non-cash investment (income) expense, net	—	98	—
Changes in operating assets and liabilities:			
Restricted cash	—	—	61
Prepaid expenses	(89)	(267)	888
Other assets	321	(324)	3
Accounts payable	(23)	489	(48)
Accrued expenses and other liabilities	(144)	1,471	(279)
Net cash used in operating activities	(19,683)	(16,740)	(16,329)
Cash flows from investing activities:			
Purchases of marketable securities	(8,256)	(18,916)	(5,274)
Sales of marketable securities	19,833	12,515	—
Purchases of property and equipment	(65)	(107)	(5)
Net cash (used in) provided by investing activities	11,512	(6,508)	(5,279)
Cash flows from financing activities:			
Proceeds from exercise of stock options	26	191	1,068
Proceeds from issuance of stock under ESPP	51	91	—
Proceeds from exercise of warrants	3	—	7,789
Repayment of loan payable	(423)	(395)	(250)
Repayment of note payable	—	—	(18)
Repurchase of warrants	(40)	—	—
Proceeds from issuance of common stock and warrants	—	29,905	14,480
Net cash (used in) provided by financing activities	(383)	29,792	23,069
Increase (decrease) in cash and cash equivalents	(8,554)	6,544	1,461
Cash and cash equivalents at beginning of period	21,464	14,920	13,459

Cash and cash equivalents at end of period	$ 12,910	$ 21,464	$ 14,920
Supplemental disclosure of cash flow information and non-cash investing and financing activities:			
Cash paid for interest	$ 71	$ 103	$ 121
Cash paid for taxes	$ —	$ —	$ —
Reclassification of derivative warrant liability to additional paid-in capital	$ —	$ —	$ 16,121
Non-cash issuance of common stock for warrants	$ 3,537	$ 90	$ 251

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, 2017, the Company has consolidated cash and cash equivalents of $12,910. 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, 2017 were prepared under the assumption that the Company will continue as a going concern. At December 31, 2017, the Company had cash and cash equivalents of $12,910. Given the Company's development plans, we estimate cash resources will be sufficient to fund our operations into the fourth 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:

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

Table of Contents

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, 2017 and 2016, cash equivalents were comprised of money market funds and other short-term investments.

Cash and cash equivalents consist of the following:

	December 31,	
(In thousands)	2017	2016
Cash	$ 23	$ 111
Money market funds	12,887	21,353
Total cash and cash equivalents	$ 12,910	$ 21,464

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, 2017, the Company had no

marketable securities. As of December 31, 2016, the Company's investment portfolio consisted 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, 2017, the Company had no marketable securities. At December 31, 2016, the aggregate fair value of the Company's marketable securities was $11,577. Gross unrealized gains and losses were insignificant for the years ended December 31, 2017 and 2016.

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).

Restricted cash

Restricted cash as of December 31, 2017 and 2016 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 16).

Table of Contents

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	3 - 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, 2017 and 2016, 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 as of December 31, 2017 or 2016. Tax years subsequent to 2013 remain open to examination by U.S. federal and state tax authorities.

The Tax Cuts and Jobs Act ("the Act") was enacted on December 22, 2017. The Act reduces the US federal corporate tax rate from 35% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred and creates new taxes on certain foreign sourced earnings. On December

Table of Contents

22, 2017, the Securities and Exchange Commission issued guidance under Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act ("SAB 118") directing taxpayers to consider the impact of the U.S. legislation as "provisional" when it does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete its accounting for the change in tax law.

At December 31, 2017, we have not completed our accounting for the tax effects of enactment of the Act; however, as described below, we have made a reasonable estimate of the effects on our existing deferred tax balances. In all cases, we will continue to make and refine our calculations as additional analysis is completed. In addition, our estimates may also be affected as we gain a more thorough understanding of the tax law.

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. On August 28, 2017, the Company implemented a strategic restructuring and as a result recorded an impairment loss of $41 related to certain fixed assets (Note 4). No impairment charge was recorded for the year ended 2016.

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, unvested restricted stock units and convertible securities are anti dilutive and therefore excluded from diluted loss per share calculations.

For the year ended December 31, 2017, 2016, and 2015, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive:

Table of Contents

	2017	2016	2015
Stock options	3,369,245	3,193,785	3,253,310
Warrants	2,166,149	3,391,439	1,156,779
Unvested restricted stock units	500,000	—	—
	6,035,394	6,585,224	4,410,089

Recent accounting pronouncements

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 interim reporting periods within each annual reporting period. The Company adopted this standard on January 1, 2017. Prior to adoption, the Company recognized share-based compensation, net of estimated forfeitures, over the vesting period of the grant. Upon adoption of ASU 2016-09, the Company elected to change its accounting policy to recognize forfeitures as they occur. The Company continues to recognize share-based compensation expense over the vesting period of the grant. The new forfeiture policy election was adopted using a modified retrospective approach with a cumulative effect adjustment of $155 recorded to accumulated deficit on the balance sheet as of January 1, 2017. Prior to January 1, 2017, the Company recognized the excess tax benefits of stock-based compensation expense as additional paid-in capital and tax deficiencies of stock-based compensation expense in the income tax provision or as additional paid-in capital to the extent that there were sufficient recognized excess tax benefits previously recognized. Previously, the excess tax benefits reduced taxes payable prior to being recognized as an increase in additional paid-in capital, and therefore the Company had not recognized certain deferred tax assets that could be attributed to tax deductions. As a result of the adoption, the deferred tax assets associated with certain net operating losses increased, which was offset by a corresponding increase in the valuation allowance and therefore the adoption of the tax-related guidance in this standard did not have an impact on our consolidated financial statements for the period ended December 31, 2017.

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 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 does not expect the adoption of this guidance to have a material impact on the financial statements.

In May 2017, the FASB issued ASU No. 2017-09, Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting ("ASU 2017-09") to clarify when to account for a change to the terms or conditions of a share-based payment award as a modification. Under this new guidance, modification accounting is required if the fair value, vesting conditions, or classification of the award changes as a result of the change in terms or conditions. ASU 2017-09

Table of Contents

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 July 2017, the FASB issued ASU No. 2017-11, Part I. Accounting for Certain Financial Instruments with Down Round Features and Part II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception ("ASU 2017-11"). Part I of this guidance applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down round features. Part II of this guidance replaces the indefinite deferrals for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities. ASU 2017-11 is effective for annual reporting periods beginning after December 15, 2018, including interim reporting periods within each annual reporting period. The Company has concluded that the adoption of this ASU will not have a material impact on the financial statements.

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 are effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within each annual reporting period. Currently, this guidance is not applicable to the Company as the Company does not generate revenue. However, the Company will adopt the guidance and evaluate the impact of adopting ASU 2014-09 on the consolidated financial statements when the Company begins to generate revenue.

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, 2017 and 2016:

(In thousands)	December 31, 2017	December 31, 2016
Cash	$ 23	$ 111
Money market funds	12,887	21,353
Marketable securities	—	11,577
Total cash, cash equivalents and marketable securities	$ 12,910	$ 33,041

Table of Contents

As of December 31, 2017, the Company had no marketable securities. As of December 31, 2016, the Company's investment portfolio consisted of cash, money market funds and 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.

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

(In thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
December 31, 2016				
Current (due within 1 year or less)				
Commercial paper	$ 4,240	—	—	$ 4,240
Corporate obligations	7,337	—	—	7,337
Total	$ 11,577	$ —	$ —	$ 11,577

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

4. PROPERTY AND EQUIPMENT

Property and equipment, net consisted of the following:

	2017	2016
Computer software and hardware	$ 241	$ 606
Research and lab equipment	508	1,895
Leasehold improvements	431	431
Office equipment	796	796
Less accumulated depreciation and amortization	(1,819)	(3,218)
Property and equipment, net	$ 157	$ 510

Depreciation expense for the years ended December 31, 2017, 2016, and 2015 was $377, $536, and $672, respectively. Maintenance and repairs are charged to expense as incurred and any additions or improvements are

capitalized. On August 28, 2017, the Company implemented a strategic restructuring and as a result wrote off $1,807 of fully depreciated assets and also recorded an impairment loss of $41 related to certain fixed assets in connection with the restructuring. The Company had no disposals for the years ended 2016.

5. INTANGIBLE ASSETS

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

	2017	2016
Patent licensing fee	$ 200	$ 200
Accumulated amortization	(139)	(122)
	$ 61	$ 78

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

Table of Contents

6. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	December 31,	
(In thousands)	2017	2016
Bonus	$ 62	$ 906
Payroll	79	126
Vacation	55	91
Severance	1,160	385
Other accrued expenses	282	451
Total accrued expenses	$ 1,638	$ 1,959

7. FAIR VALUES OF ASSETS AND LIABILITIES

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

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

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

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

The Company uses valuation methods and assumptions that consider, among other factors, the fair value of the underlying stock, risk free interest rate, volatility, expected life, and dividend rates in estimating 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, 2017			
(In thousands)	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	$ 12,887	$ —	$ —	$ 12,887
Marketable securities	$ —	$ —	$ —	$ —
Derivative warrant liability	$ —	$ 4	$ —	$ 4

	At December 31, 2016			
(In thousands)	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

8. 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

Table of Contents

on May 1, 2015, equal monthly principal payments of $41 are due until loan maturity. Therefore, for the years ending December 31, 2018, and 2019, principal payments of $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, 2017, 2016, and 2015 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 $71, $99, and $126 for the years ended December 31, 2017, 2016, and 2015, respectively.

At December 31, loans payable consisted of the following:

	December 31,	
	2017	2016
MassDev Loan	$ 852	$ 1,275
Less: current portion	(452)	(423)
	$ 400	$ 852

9. 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, 2017, the Company had U.S. federal and Massachusetts net operating loss carryforwards of $117,298 and $109,183, 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 $991 and $230, respectively, at December 31, 2017, which will begin to expire in 2022 unless previously utilized.

On December 22, 2017, the Tax Cuts and Jobs Act ("the Act") was enacted in the United States. The Act reduces the U.S. federal corporate tax rate from 35% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred and creates new taxes on certain foreign sourced

earnings. At December 31, 2017, we have not completed our accounting for the tax effects of enactment of the Act, including the effects on our existing deferred tax balances. In addition to the reduction in the federal corporate tax rate, which we have accounted for with provision estimates at December 31, 2017, we continue to analyze the provisions of tax reform that become effective for the Company in 2018 including the provisions related to Global Intangible Low Taxed Income, Foreign Derived Intangible Income, Base Erosion Anti-Abuse Tax, as well as other provisions which would limit the deductibility of future expenses.

As a result of the Act, we remeasured certain deferred tax assets and liabilities based on the rates at which they are anticipated to reverse in the future, which is generally 21%. This resulted in a decrease to our gross deferred tax assets and a corresponding decrease in our valuation allowance of $15,521. Any items reported are done so using provisional amounts until the initial accounting required by the Act is complete. Additional time and resources are needed to ensure the correct implementation of the Act.

Table of Contents

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

	December 31, 2017	2016
Net operating loss carryforward	$ 31,533	$ 37,245
Research and development credit carryforward	1,173	1,065
Stock-based compensation	2,828	5,235
Depreciation and amortization	71	31
Accrued expenses	357	264
Charitable contributions	27	63
Subtotal	35,989	43,903
Valuation allowance	(35,989)	(43,903)
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. During the year ending December 31, 2017, the Company adopted ASU 2016-09, Improvements to Employee Share-Based Payment Accounting. As part of the adoption, the Company recorded through retained earnings additional deferred tax assets of $642 related to previously unrecognized tax losses with an equal and offsetting adjustment to the Company's valuation allowance. The net impact of the adoption on the Company's deferred tax assets was $0. In the years ended December 31, 2017 and 2016, the valuation allowance decreased by $7,914 and increased $9,406, respectively.

The Company has no uncertain tax positions at December 31, 2017 and 2016 that would affect its effective tax rate. The Company does not anticipate a significant change in the amount of uncertain tax positions over the next twelve months. Since the Company is in a loss carryforward position, the Company is generally subject to U.S. federal and state income tax examinations by tax authorities for all years for which a loss carryforward is available.

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

	December 31, 2017		2016		2015	
Statutory rate	(34.0)	%	(34.0)	%	(34.0)	%
State taxes, net of benefit	(4.7)	%	(5.4)	%	(3.5)	%
Permanent differences:						
Derivative losses	2.9	%	(0.9)	%	11.0	%

Other	1.1	%	0.2	%	0.3	%
Research and development tax credit	(0.2)	%	(0.5)	%	(0.4)	%
Other	1.4	%	0.5	%	0.4	%
Adoption of ASU 2016-09	7.4	%	—	%	—	%
Increase / (decrease) in valuation reserve	(32.0)	%	40.1	%	26.2	%
Change in federal tax rate	58.1	%	—	%	—	%
Effective tax rate	0.0	%	0.0	%	0.0	%

10. COMMON STOCK

The Company has authorized 100,000,000 shares of common stock, $0.00001 par value per share, of which 34,274,776, shares were issued and outstanding as of December 31, 2017 and 32,044,087 shares were issued and outstanding as of December 31, 2016.

During the year ended December 31, 2017, the Company issued an aggregate of 89,387 shares of common stock upon the exercise of stock options and received cash proceeds from such exercises of $26.

During the year ended December 31, 2017, the Company issued an aggregate of 3,464 shares of common stock upon the exercise of warrants and received cash proceeds from such exercises of $3.

Table of Contents

During the year ended December 31, 2017, the Company issued an aggregate of 98,319 shares of common stock with a fair value of $183 to the Company's 401(k) plan as a matching contribution.

During the year ended December 31, 2017, the Company issued an aggregate of 17,750 shares of common stock under the Company's Employee Stock Purchase Plan (the "ESPP") and received cash proceeds of $51.

During the year ended December 31, 2017, the Company issued an aggregate of 2,021,419 shares of common stock to certain holders of warrants, dated May 9, 2014, in exchange for their warrants to purchase an aggregate of 577,548 shares of common stock. The Company did not receive any cash proceeds from the warrant exchanges (see Note 13).

On January 25, 2018, we entered into a purchase and a registration rights agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"), under which we have the right to sell up to $15,000 in shares of our common stock, $0.00001 par value per share, to Lincoln Park over a twenty-four-month period, subject to certain limitations and conditions set forth in the purchase agreement and registration rights agreement. In accordance with the terms of the purchase agreement, at the time we signed the purchase agreement and the registration rights agreement, we issued 429,800 shares to Lincoln Park as consideration for its commitment to purchase shares of our common stock under the purchase agreement (see Note 19).

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, 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 ESPP and received cash proceeds of $91.

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.

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.

Table of Contents

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 $50,000 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.

Common Stock Reserves

As of December 31, 2017, the Company had the following reserves established for the future issuance of common stock as follows:

Reserves for the exercise of warrants	2,166,149
Reserves for the exercise of stock options	3,369,245
Reserves for the vesting of restricted stock units	500,000
Total Reserves	6,035,394

11. 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 10) 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. Through the date of the warrant exchange (Note 13), 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. As of December 31, 2017 the derivative warrant liability was insignificant. 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, 2017, 2016, and 2015, a (gain) loss of $2,267, $(593) and $10,804, 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, 2017 and 2016 was $4 and $1,314, 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:

	December 31,					
	2017		2016		2015	
Risk-free interest rate	1.91	%	1.20	%	0.65	%
Expected dividend yield	0	%	0	%	0	%
Contractual term	1.35	years	2.4	years	3.4	years
Expected volatility	82	%	89	%	100	%

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

Table of Contents

The table below presents the changes in derivative warrant liability during the years ended December 31, 2017, 2016, and 2015:

	Year Ended December 31,		
	2017	2016	2015
Balance at beginning of year	$ 1,314	$ 1,907	$ 7,224
Increase in derivative liability prior to warrant exchange	3,029	—	—
Reduction in derivative liability due to warrant exchange	(3,537)	—	—
Repurchase of warrants	(40)	—	—
Fair value of derivative warrant liability reclassified to additional paid in capital	—	—	(16,121)
Increase (decrease) in the fair value of warrants	(762)	(593)	10,804
Balance at end of year	$ 4	$ 1,314	$ 1,907

12. 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, 2017, there were options to purchase an aggregate of 46,476 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, 2017, 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, 2017, there were outstanding options to purchase an aggregate of 1,878,125 and 1,444,644 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.

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, 2017, approximately $3 of employee payroll deductions had

Table of Contents

been withheld since July 1, 2017, 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, 2017 and 2016 was $14 and $46, respectively, and is included in stock-based compensation expense. In January 2018, 4,691 shares that were purchased as of December 31, 2017 were issued under the ESPP.

Share based compensation

For the years ended December 31, 2017, 2016 and 2015, the Company recorded stock based compensation expense of $4,106, $5,063 and $4,666, 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 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, 2017	2016	2015
Risk-free interest rate	1.69 - 2.36%	1.20 - 1.52%	1.53 - 1.89%
Expected dividend yield	0%	0%	0%
Expected term (employee grants)	6.22 Years	5.99 years	6.00 years
Expected volatility	104%	111%	116%

A summary of option activity as of December 31, 2017 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, 2016	3,193,785	$ 7.52		
Granted	1,439,463	$ 3.94		
Forfeited	(1,174,616)	$ 6.40		
Exercised	(89,387)	$ 0.29		
Outstanding at December 31, 2017	3,369,245	$ 6.57	7.14	$ 22
Vested at December 31, 2017	2,224,246	$ 7.54	6.22	$ 22
Vested and expected to vest at December 31, 2017	3,369,245	$ 6.57	7.14	$ 22

The weighted average grant date fair value of options granted during the years ended December 31, 2017, 2016 and 2015 was $2.54, $5.23, and $7.37 per share, respectively. The total fair value of options that vested in the years ended December 31, 2017, 2016, and 2015 was $3,837, $5,179, and $5,144, respectively. As of December 31, 2017, there was $3,516 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 2.38 years at December 31, 2017.

Table of Contents

Restricted Stock