INVIVO THERAPEUTICS HOLDINGS CORP.
Form 10-K
April 01, 2019
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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, 2018
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	Name of exchange on which registered
Common Stock, $0.00001 par value	The Nasdaq Capital 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 every Interactive Data File required to be submitted 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 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.

Large accelerated filer	Accelerated filer	Non accelerated filer	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, 2018, the last business day of the registrant's most recently completed second fiscal quarter, was $6,914,896 based on a per share price of $1.70, which was the closing price of the registrant's common stock on the Nasdaq Capital Market the last trading date prior to June 30, 2018.

As of March 22, 2019, the number of shares outstanding of the registrant's common stock, $0.00001 par value per share, was 9,311,070.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2019 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The registrant intends to file such proxy statement with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates.

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INVIVO THERAPEUTICS HOLDINGS CORP.

ANNUAL REPORT ON FORM 10 K

FOR THE YEAR ENDED DECEMBER 31, 2018

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PART I

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, 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

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

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

Item 1. BUSINESS

Overview

We are a research and clinical-stage biomaterials and biotechnology company with a focus on treatment of spinal cord injuries, 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.

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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 an active 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 2 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 through 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.

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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 2 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 2 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

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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 2 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 5 subjects in up to 6 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 3 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 5 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: the “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, or IDE, 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 6-month primary endpoint visit, and 3 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, or (NLI), SCI. The primary endpoint was defined as the proportion of patients achieving an improvement of at least 1 AIS grade at 6 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 a Humanitarian Device Exemption, or 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 1 AIS grade at the 6-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 6 month primary endpoint visit. Of these 16, 7 had improved from complete AIS A SCI to incomplete SCI (2 patients to AIS C and 5 patients to AIS B) at the 6 month primary endpoint visit and 9 had not demonstrated improvement at that visit. 3 of the 7 patients who improved were assessed to have AIS B SCI at the

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6 month primary endpoint and were later assessed to have improved to AIS C SCI at the 12 or 24-month visits. 2 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 6 month examination. 1 of these 2 was then assessed at the 6 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 1 source of comparator data, we initiated the Contemporary Thoracic SCI Registry Study, or the CONTEMPO Registry Study. The CONTEMPO Registry Study utilizes 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, or NACTN, as well as the Model Systems Registry and the European Multicenter Study about Spinal Cord Injury, or EMSCI. We have submitted a protocol for the CONTEMPO Registry Study to the FDA and we announced top-line findings from CONTEMPO in March 2018 from a total of 170 patients from the 3 registries consisting of: 12 individuals from NACTN, 64 from EMSCI, and 94 from the Model Systems Registry. AIS conversion rates at approximately 6 months post-injury varied from 16.7% – 23.4% across the 3 registries. In 2 of the registries, there was a skew of the patient population to low (T10- T12) thoracic injuries, representing 46-47% of the registry population. This compares to just 4 out of 16 patients (25%) in follow-up in the INSPIRE study with low thoracic injuries. Patients with low thoracic injuries are known to have the best prognoses, and the conversion rates were the highest in the low thoracic group in all 3 registries and the INSPIRE study. When all 3 registries were normalized to the INSPIRE patient population distribution across T2-T5, T6-T9 and T10-T12 injury groups, the normalized conversion rate for CONTEMPO registries ranged from 15.5%-20.6%. 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 of the 2 study arms, which we refer to as the Scaffold Arm and the Comparator Arm. Patients in the Comparator Arm will receive the 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 expect to conduct the INSPIRE 2.0 Study at up to 25 sites in the United States. Enrolling patients in the INSPIRE 2.0 Study will also require the approvals of the institutional review boards, or IRBs, at each clinical

site. We estimate that from study initiation, enrollment will take approximately 18 months, and the total time to completion of the INSPIRE 2.0 Study is estimated to be 2 years from study initiation. We anticipate that the first patient in the INSPIRE 2.0 Study will be enrolled in the second quarter of 2019.

The primary endpoint is defined as the proportion of patients achieving an improvement of at least 1 AIS grade at 6 months post-implantation. Assessments of AIS grade are at hospital discharge, 3 months, 6 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 1 grade on AIS assessment at the 6-month primary endpoint follow-up visit between the Scaffold Arm and the Comparator Arm must be equal to or greater than 20%. In 1 example, if 50% of subjects in the Scaffold Arm have an improvement of AIS grade at the 6-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 6-month primary endpoint and 30% of subjects in the Comparator Arm have an improvement, then the difference in the proportion of subjects who

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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, and quality of life.

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. Similarly, while our 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 3 modules: a preclinical studies module, a manufacturing module, and a clinical data module. As part of its review process, the FDA reviews each module, 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 all 3 modules, 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 plan to submit an updated first module in the fourth quarter of 2019. 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 Boston Children's Hospital or BCH and Massachusetts Institute of Technology or 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 6 issued United States patents and 18 issued international patents expiring between 2019 and 2027, and 1 pending United States patent application and 1

pending international patent application.

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

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(i) filing with the FDA of the first investigational new drug application and IDE application for a product that uses the licensed technology; (ii) enrollment of the first patient in Phase II testing for a product that uses the licensed technology; (iii) enrollment of the first patient in Phase III testing for a product that uses the licensed technology; (iv) FDA approval of the first new drug application or related application for a product that uses the licensed technology; and (v) first market approval in any country outside the United States for a product that uses the licensed technology. Each year prior to the release of a licensed product, we are also required to pay a maintenance fee for the BCH License. Further, we are required to make ongoing payments based on any sublicenses we grant to manufacturers and distributors. Following commercialization, we are required to make ongoing royalty payments equal to a percentage in the low single digits of net sales of any product that uses the licensed technology.

In addition to the rights we license under the BCH License, we have additional rights relating to the Neuro-Spinal Scaffold implant. Together with MIT, we co-own U.S. patent No. 1,013,785 (“Poly((lactic-co-glycolic acid)-b-lysine) and process for synthesizing a block copolymer of PLGA and PLL- (poly-e-cbz-l-lysine)”), which expires in 2033.

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

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subcontractors. Failure by manufacturers or their suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities. Potential FDA enforcement actions include:

- warning letters, fines, injunctions, consent decrees, and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications for repair, replacement, or refunds;
- recall, detention, or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance on HDE or premarket approval applications, 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 1 of 3 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 1 and 3 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

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of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel.

Humanitarian Device Exemption (HDE)

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 a 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, a 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;

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

- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of 1 of our cleared devices;

- approval of product modifications that affect the safety or effectiveness of 1 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.

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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 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 measures 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.

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

Financial Information and Research and Development Expenditures

We have incurred net losses each year since our inception, including net losses of $23.4 million for the year ended December 31, 2018 and $26.7 million for the year ended December 31, 2017. 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 $4.9 million and $11.1 million in 2018 and 2017, 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 1 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 2 fully operational manufacturing cleanrooms located at our facility in Cambridge, Massachusetts. These 2 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 2 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 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.

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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.

Employees

As of December 31, 2018, we had 6 employees. None of our employees are 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, human resources, clinical 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 as a Nevada corporation. On October 26, 2010, we acquired the business of InVivo Therapeutics Corporation, which was founded in 2005 as a Delaware corporation, 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.

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.

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Item 1A. RISK FACTORS

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

Risks Related to Our Financial Position and Need for Additional Capital

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

We have incurred net losses each year since our inception, including net losses of $23.4 million for the year ended December 31, 2018 and $26.7 million for the year ended year ended December 31, 2017. As of December 31, 2018, we had an accumulated deficit of $207.3 million. We have a limited operating history on which to base an evaluation of our business and investors should consider the risks and difficulties frequently encountered by early-stage companies in new and rapidly evolving markets, particularly companies engaged in the development of medical devices. To date, we have not commercialized any products or generated any revenues from the sale of products, and we do not expect to generate any product revenues in the foreseeable future. We do not know whether or when we will generate revenue or become profitable. Moreover, we may allocate significant amounts of capital towards products and technologies for which market demand is lower than anticipated and, as a result, may not achieve expectations or may elect to abandon such efforts.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities related to our Neuro-Spinal Scaffold implant. Overall, we expect our research and development expenses to be substantial and to increase for the foreseeable future as we continue the development and clinical investigation of our current and future products. 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.

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

Our financial statements as of December 31, 2018 were prepared under the assumption that we will continue as a going concern. At December 31, 2018, we had cash and cash equivalents of $16.7 million. We estimate that our existing cash resources will be sufficient to fund our operations into the first quarter of 2020. 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 may not be sufficient to complete clinical development of our Neuro-Spinal Scaffold implant, including the resources needed to reach submission of the HDE application to the FDA. If we are unable to raise additional 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 April 1, 2019 included elsewhere in this Form 10-K.

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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. The FDA has approved the INSPIRE 2.0 Study. However, we may not be able to pursue the currently defined clinical path forward successfully, or in a timely manner or that is aligned with our cash resources. The INSPIRE 2.0 Study may not be successfully completed or may take longer than anticipated because of any number of factors, including potential delays in the enrollment of subjects in the study, the availability of scaffold implants 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 the INSPIRE 2.0 Study and any other clinical trial of our Neuro-Spinal Scaffold implant will continue to require the approval of the institutional review boards, or 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, 2 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 6-month examination. Of these 2 patients, 1 patient had converted back to AIS B and the other remained at AIS A at the 6-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 the INSPIRE 2.0 Study, and will also implement procedures in any future clinical 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 2 observations relating to our 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

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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.

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 have experienced and may continue to experience delays with our 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.

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;

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- 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.

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

We expect our expenses will increase in connection with our ongoing activities, particularly as we conduct our INSPIRE 2.0 Study, and as we 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.

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 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;

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- 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.

Our independent registered public accounting firm expressed substantial doubt as to our ability to continue as a going concern in its report filed herewith. Although we completed a public offering of shares of our common stock and warrants to purchase shares of our common stock in June 2018 which resulted in net proceeds to us, after deducting the underwriting discounts and commissions and other offering expenses, of $13.5 million, if we are not successful in raising additional capital, we may not be able to continue as a going concern.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, and other third party funding alternatives including license and collaboration agreements. To raise additional capital or pursue strategic transactions, we may in the future sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock, which will dilute the ownership interest of our current stockholders, and the terms of these securities may include

liquidation or other preferences that adversely affect the rights of our current stockholders. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams or research programs, or grant licenses on terms that may not be favorable to us or that may reduce the value of our common stock. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce, or terminate our product development or commercialization efforts for our Neuro-Spinal Scaffold implant or any other product candidates that we develop or acquire.

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 revised the Internal Revenue Code of 1986, as amended, which we refer to as the Code. The federal income tax law, among other things, contained 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 net operating losses, or 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

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income tax rate, the long-term impact of this federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will continue to respond to the federal tax law. The impact of this tax reform on holders of our common stock also remains 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.

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, 2018 can generally be carried back 2 years and carried forward for up to 20 years and can be applied to offset 100% of taxable income in such years. Under 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 continue to respond to the recently 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, respectively, of the Code. 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.

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

We continue to actively evaluate business partnerships and 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.

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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 1 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 pre-market approval, or 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 regulatory approval process required by the FDA 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.

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 the HDE regulatory pathway 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.

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

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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 1 AIS grade by 6 months post-implantation. While we expect The INSPIRE Study to serve as 1 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 1 AIS grade at 6 months post-implantation. The definition of study success is that the difference in the proportion of subjects who demonstrate an improvement of at least 1 grade on AIS assessment at the 6-month primary endpoint follow-up visit between the Scaffold Arm and the Comparator Arm must be equal to or greater than 20%. While our 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 1 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 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, AIS conversion rates at approximately 6 months post-injury across the 3 registries used in CONTEMPO varied from 16.7% – 23.4%, which are higher than the approximately 15.5% conversion 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.

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.

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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 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, a 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 1 center within the FDA. We cannot be sure that the FDA will not select to have our combination products reviewed and regulated by only 1 FDA center and/or different legal authority, in which case the path to regulatory approval would be different and could be lengthier and more costly. If the FDA does not approve or clear our products in a timely fashion, or at all, our business and financial condition will be adversely affected.

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

In general, the biotechnology industry is subject to intense competition and rapid and significant technological change. We have many potential competitors, including major drug companies, specialized biotechnology firms, academic institutions, government agencies, and private and public research institutions. Many of these competitors have significantly greater financial and technical resources than us, and superior experience and expertise in research and development, preclinical testing, design and implementation of clinical trials, regulatory processes and approval for products, production and manufacturing, and sales and marketing of approved products. Large and established companies compete in the biotechnology market. In particular, these companies have greater experience and expertise in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale, and marketing approved products. Smaller or early-stage companies and research institutions may also prove to be significant competitors, particularly if they have collaborative arrangements with larger and more established biotechnology companies. We will also face competition from these parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, and registering subjects for clinical trials.

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In order to effectively compete, we will have to make substantial investments in development, clinical testing, manufacturing, and sales and marketing, or partner with 1 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.

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.

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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 1 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 that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

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

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. 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;

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- 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. A HUD designation was granted for the Neuro-Spinal Scaffold implant in 2013, opening the HDE pathway.

In the PMA 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 1 to 3 years, or even longer, from the time the application is submitted to the FDA until an approval is obtained.

An HDE application is similar in form and content to a PMA 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.

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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.

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 1 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 1 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

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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.

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 Patient Protection and Affordable Care Act, or 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.

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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.

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

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

Our success, in large part, depends on our ability to protect and maintain the proprietary nature of our technology. We and our licensors must prosecute and maintain our existing patents and obtain new patents. Some of our proprietary information may not be patentable, and there can be no assurance that others will not utilize similar or superior solutions to compete with us. We cannot guarantee that we will develop proprietary products that are patentable, and that, if issued, any patent will give a competitive advantage or that such patent will not be challenged by third parties. The process of obtaining patents can be time consuming with no certainty of success, as a patent may not issue or may not have sufficient scope or strength to protect the intellectual property it was intended to protect. We cannot assure you that our means of protecting our proprietary rights will suffice or that others will not independently develop competitive technology or design around patents or other intellectual property rights issued to us. Even if a patent is issued, it does not guarantee that it is valid or enforceable. Any patents that we or our licensors have obtained or obtain in the future may be challenged, invalidated, or unenforceable. If necessary, we may initiate actions to protect our intellectual property, which can be costly and time consuming.

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 1 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

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technology. We may not be able to obtain any such licenses that may be required on reasonable financial terms, if at all, and cannot be sure that the patents underlying any such licenses will be valid or enforceable. There may be rights that we are not aware of, including applications that have been filed but not published that, when issued, could be asserted against us. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research and development of the product that is the subject of the suit. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our trade secrets or other confidential information could be compromised by disclosure during this type of litigation.

Risks Related to our Dependence on Third Parties

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

The near and long-term viability of our products will depend, in part, on our ability to successfully establish new strategic collaborations with biotechnology companies, hospitals, insurance companies, and government agencies. Establishing strategic collaborations is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory, or intellectual property position. If we fail to establish a sufficient number of collaborations on acceptable terms, we may not be able to commercialize our products or generate sufficient revenue to fund further research and development efforts.

Even if we establish new collaborations, these relationships may never result in the successful development or commercialization of any of our product candidates for reasons both within and outside of our control.

There are a limited number of suppliers that can provide materials to us. Any problems encountered by such suppliers may detrimentally impact us.

We rely on third-party suppliers and vendors for certain of the materials used in the manufacture of our products or other of our product candidates. Any significant problem experienced by 1 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.

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 and on January 14, 2019,

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we appointed Richard Christopher as Chief Financial Officer and Treasurer. The loss of any members 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 may face, and in the past have faced, lawsuits, which could divert management's attention and harm our business.

We may face lawsuits, including class action or securities derivative lawsuits. For example, we were previously the subject of a securities derivative lawsuit and securities class action lawsuit, both of which were dismissed in January

2017. 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.

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.

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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.

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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.

Our operations and reputation may be impaired if our information technology systems fail to perform adequately or if we are the subject of a data breach or cyber-attack.

Our information technology systems are important to operating our business. We rely on our information technology systems, some of which are or may be managed or hosted by or out-sourced to third party service providers, to manage our business data and other business processes. If we do not allocate and effectively manage the resources necessary to build, sustain, and protect appropriate information technology systems and infrastructure, or we do not effectively implement system upgrades or oversee third party service providers, our business or financial results could be negatively impacted. The failure of our information technology systems to perform as we anticipate could disrupt our business and could result in transaction or reporting errors and processing inefficiencies causing our business and results of operations to suffer.

Furthermore, our information technology systems may be vulnerable to cyber-attacks or other security incidents, service disruptions, or other system or process failures. Such incidents could result in unauthorized access to information including vendor, consumer or other company confidential data as well as disruptions to operations. We have experienced in the past, and expect to continue to experience, cybersecurity threats and incidents, although to date none has been material. To address the risks to our information technology systems and data, we maintain an information security program that includes updating technology, developing security policies and procedures, implementing and assessing the effectiveness of controls, conducting risk assessments of third-party service providers and designing business processes to mitigate the risk of such breaches. There can be no assurance that these measures will prevent or limit the impact of a future incident. Moreover, the development and maintenance of these measures requires continuous monitoring as technologies change and efforts to overcome security measures evolve. If we are unable to prevent or adequately respond to and resolve an incident, it may have a material, negative impact on our

operations or business reputation, and we may experience other adverse consequences such as loss of assets, remediation costs, litigation, regulatory investigations, and the failure by us to retain or attract customers following such an event. Additionally, we rely on services provided by third-party vendors for certain information technology processes and functions, which makes our operations vulnerable to a failure by any one of these vendors to perform adequately or maintain effective internal controls

Risks Related to Investment in Our Securities

The price of our common stock has been and may continue to be 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;

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- 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.

In the foreseeable future, we do not intend to pay cash dividends on shares of our common stock so any investor gains will be limited to the value of our shares

We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any gains to stockholders will therefore be limited to the increase, if any, in our share price

In the event that we fail to satisfy any of the listing requirements of the Nasdaq Capital Market, our common stock may be delisted, which could affect our market price and liquidity.

Our common stock is listed on the Nasdaq Capital Market. For continued listing on the Nasdaq Capital Market, we will be required to comply with the continued listing requirements, including the minimum market capitalization standard, the corporate governance requirements and the minimum closing bid price requirement, among other requirements. For example, we were previously listed on the Nasdaq Capital Market and on January 23, 2018 we received a deficiency letter from the Listings Qualifications Department of the Nasdaq Stock Market notifying us that, for the prior 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 Capital Market. Although we regained compliance with the Bid Price Rule as a result of the reverse stock split we effected on April 16, 2018, we received a notification from the Listing Qualifications Department of the Nasdaq Stock Market on May 11, 2018, notifying us that, based on our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, our stockholders' equity was $8,323,000, and therefore, the we were not in compliance with the minimum stockholders' equity standard which required a minimum of $10,000,000 in stockholders' equity. We elected to transfer to the Nasdaq Capital Market, and the transfer was effective June 19, 2018.

On August 15, 2018, we received a written notification from the Listing Qualifications Department of the Nasdaq Stock Market notifying us that, based on our Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, our stockholders' equity was $(1,909,000), and therefore, we were not in compliance with Nasdaq Listing Rule 5550(b)(1), which requires a $2,500,000 minimum stockholders' equity standard. Total stockholders' deficit at June 30, 2018 was primarily driven by derivative accounting on the warrants issued as part of our June 2018 public offering. In accordance with such notice, we were requested to provide to Nasdaq, on or before October 1, 2018, our specific plan to regain compliance with all Nasdaq Capital Market listing requirements and our time frame to complete our plan. On October 1, 2018, we submitted a plan to regain compliance with the continued listing requirements of the Nasdaq Capital Market, and Nasdaq had granted us an extension until November 14, 2018 to evidence compliance with all Nasdaq Capital Market listing requirements. On November 9, 2018, we received a written notification from the Listing Qualifications Department notifying us that, based on our Quarterly Report on Form 10-Q for the quarter ended

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September 30, 2018, our stockholders' equity was $18,482,000, and therefore, Nasdaq had determined that the we had regained compliance with Listing Rule 5550(b)(1), which requires a $2,500,000 minimum stockholders' equity standard.

In the event that we fail to satisfy any of the listing requirements of the Nasdaq Capital Market our common stock may be delisted. If our securities are delisted from trading on the Nasdaq Capital Market, and we are not able to list our securities on another exchange our securities could be quoted on the OTC Bulletin Board or on the "pink sheets." As a result, we could face significant adverse consequences including:

- a limited availability of market quotations for our securities;

- a determination that our common stock is a "penny stock," which would require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;

- a limited amount of news and analyst coverage; and;

- a decreased ability to issue additional securities (including pursuant to short-form registration statements on Form S-3 or obtain additional financing in the future).

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 3 classes, with 3-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 2 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 2 year moratorium period, additional stockholder approvals or fair value requirements must be met by the interested shareholder up to 4

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.

We have identified a material weakness in our internal control over financial reporting. If we fail to develop and maintain an effective system of internal controls over financial reporting, we may not be able to accurately report our financial results in a timely manner, which may adversely affect investor confidence in our company.

In connection with the audit of our consolidated financial statements as of and for the year ended December 31, 2018, our management identified a material weakness in our internal controls over financial reporting, as defined in the standards established by the Public Company Accounting Oversight Board of the United States. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness related to a lack of timely and ongoing entity-level risk

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assessment to identify and assess changes that could significantly impact the system of internal control over financial reporting and significant deficiencies in our Information Technology General Controls related to areas of user access, change management, and computer operations over certain systems that support the financial reporting process. Please see “Item 9A. Controls and Procedures—Internal Control Over Financial Reporting” for information regarding the material weakness and our remediation efforts.

We are currently taking actions to remediate the material weakness and are implementing additional processes and controls designed to address the underlying causes that led to the deficiencies. There can be no assurance that we will be able to successfully remediate the identified deficiencies, or that we will not identify additional control deficiencies or material weakness in the future. If we are unable to successfully remediate our existing or any future material weakness in our internal control over financial reporting, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities laws and Nasdaq listing requirements regarding the timely filing of periodic reports, investors may lose confidence in our financial reporting and the price of our shares may decline.

We are a “smaller reporting company,” and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are considered a “smaller reporting company” under Rule 12b-2 of the Exchange Act. We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company also mean our auditors are not required to review our internal control over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our common stock prices may be more volatile. We will remain a smaller reporting company until our public float exceeds $250 million or our annual revenues exceed $100 million with a public float greater than $700 million.

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Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

We sublease 5,104 square feet of space in Cambridge, Massachusetts, which is used primarily for corporate, manufacturing, and research and development functions. The sublease commenced in May 2018 and is for a term of 5 years and 6 months.

Item 3. LEGAL PROCEEDINGS

In the ordinary course of business, we may be subject to litigation from time to time. There is no current, pending or, to our knowledge, threatened litigation or administrative action to which we are a party or of which our property is the subject (including litigation or actions involving our officers, directors, affiliates, or other key personnel, or holders of record or beneficially of more than 5% of any class of our voting securities, or any associate of any such party) which in our opinion has, or is expected to have, a material adverse effect upon our business, prospects financial condition or operations.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

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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 Capital 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.

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 22, 2019, we had approximately 282 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

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information under this item.

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Item 6. SELECTED FINANCIAL DATA

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information under this item.

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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-25 reverse stock split of our outstanding shares of common stock that occurred on April 16, 2018.

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 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.

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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 10 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 11, “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 previously contained anti dilution provisions. These warrants did not meet the requirements for classification as equity and were thus recorded as derivative warrant liabilities. We used valuation methods and assumptions that considered, 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 10, “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 were initially recorded at fair value, with subsequent changes in fair value charged (credited) to operations during each reporting period. The fair value of such derivative warrant liabilities was most sensitive to changes in the fair value of the underlying common stock and the estimated volatility of our common stock. As of December 31, 2018, we did not have any liability classified warrants. See Note 10, “Derivative Instruments,” in the Notes to Consolidated Financial Statements in Item 8 of this Annual Report on Form 10-K for more information about the derivative activity during the year.

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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 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.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 we expect to be entitled in exchange for those goods or services. 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. Collectively, these standards are effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within each annual reporting period. We adopted ASU 2014-09 on January 1, 2018, and it did not have any impact on the financial position, results of operations or disclosures, as we currently do not generate any revenue.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments - Overall (Subtopic 825-10) - Recognition and Measurement of Financial Assets and Financial Liabilities (“ASU 2016-01”). ASU 2016-01 is intended to improve the recognition and measurement of financial instruments by: requiring equity investments to be measured at fair value with changes in fair value recognized in net income; requiring public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requiring separate presentation of financial assets and financial liabilities by measurement category and form of financial asset on the balance sheet or the accompanying notes to the financial statements; eliminating the requirement for public business entities to disclose the

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method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured and amortized at cost on the balance sheet; and requiring a reporting organization to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the organization has elected to measure the liability at fair value in accordance with the fair value option for financial instruments. ASU 2016-01 is effective for annual periods and interim periods within those annual periods, beginning after December 15, 2017. The amendments should be applied by means of a cumulative-effect adjustment to the balance sheet as of the beginning of the fiscal year of adoption. The amendments related to equity securities without readily determinable fair values (including disclosure requirements) should be applied prospectively to equity investments that exist as of the date of adoption. In February 2018, the FASB issued ASU No. 2018-03 which includes technical corrections and improvements to clarify the guidance in ASU No. 2016-01. We adopted ASU 2016-01 on January 1, 2018, and it did not have any impact on the accounting for equity investments, fair value disclosures or other disclosure requirements.

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 FASB has subsequently issued amendments to the guidance, including the addition of an optional transition method and provided clarifications to address potential narrow-scope implementation issues. The adoption of ASU 2016-02 will result in an increase to our consolidated balance sheets for right-of-use assets and lease liabilities. We adopted ASU 2016- 02 effective January 1, 2019 and elected the optional transition method for adoption. We also took advantage of the transition package of practical expedients permitted within ASU 2016-02, which among other things, allowed us to carryforward historical lease classifications. We also elected to keep leases with an initial term of 12 months or less off of the balance sheet as a policy election and will recognize those lease payments in the consolidated statements of operations on a straight-line basis over the lease term. Based on our current lease portfolio, we estimate that the adoption of this standard will result in approximately $1.5 million of additional assets and liabilities being reflected on our consolidated balance sheets on January 1, 2019; however, there will not be a material impact to our consolidated statement of operations or cash flows.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments (“ASU No. 2016-15”), which clarifies the classification of certain cash receipts and cash payments in the statement of cash flows, including debt prepayment or extinguishment costs, settlement of contingent consideration arising from a business combination and insurance settlement proceeds. We adopted ASU 2016-15 on January 1, 2018, and it did not result in any changes to the presentation of amounts shown on the consolidated statements of cash flows for all periods presented.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (A Consensus of the FASB Emerging Issues Task Force) (“ASU No 2016-18”). The amendments in this Update require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. We adopted ASU No. 2016-18 in the first quarter of 2018 and applied the guidance retrospectively to the prior period consolidated

statement of cash flows. The following table provides a reconciliation of cash, cash equivalents, and restricted cash within the statement of financial position that sum to the total of the same such amounts shown in the statement of cash flows.

(In thousands)	December 31, 2018	December 31, 2017
Cash and cash equivalents	$ 16,660	$ 12,910
Restricted cash included in current assets	4	361
Restricted cash included in other non-current assets	110	—
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 16,774	$ 13,271

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,

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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 adopted ASU 2017-09 on January 1, 2018 and it did not have a material effect on the financial position, results of operations or disclosures.

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 ASU 2017-11 will not have a material impact on our financial statements.

In February 2018, the FASB issued Accounting Standards Update No. 2018-02, Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income. This Update relates to the impacts of the tax legislation commonly referred to as the Tax Reform Act. The guidance permits the reclassification of certain income tax effects of the Tax Reform Act from other comprehensive income to retained earnings (stranded tax effects). The guidance also requires certain new disclosures. The guidance is effective for annual periods beginning after December 15, 2018, and interim periods within those reporting periods. Early adoption is permitted. Entities may adopt the guidance using 1 of 2 transition methods; retrospective to each period (or periods) in which the income tax effects of the Tax Reform Act related to the items remaining in other comprehensive income are recognized or at the beginning of the period of adoption. We are currently evaluating the impact that the guidance may have on our consolidated financial statements.

In June 2018, the FASB issued Accounting Standards Update No. 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting which is intended to reduce cost and complexity and to improve financial reporting for nonemployee share-based payments. The amendment is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. We do not expect the adoption of this Accounting Standard to have a material effect on our consolidated financial statements.

In July 2018, the FASB issued Accounting Standards Update No. 2018-09, Codification Improvements which clarifies, corrects errors in, and makes improvements to several Codification Topics, including to:

- Clarify when excess tax benefits should be recognized for share-based compensation awards
- Remove inconsistent guidance in income tax accounting for business combinations
- Clarify the circumstances when derivatives may be offset

- Clarify the measurement of liability or equity-classified financial instruments when an identical asset is held as an asset
- Allow portfolios of financial instruments and nonfinancial instruments accounted for as derivatives to use the portfolio exception to valuation

The transition and effective date guidance is based on the facts and circumstances of each amendment. Some of the amendments in this Update do not require transition guidance and will be effective upon issuance of this Update. However, many of the amendments in this Update do have transition guidance with effective dates for annual periods beginning after December 15, 2018. We are currently evaluating the impact that the guidance may have on our consolidated financial statements.

In August 2018, the FASB issued Accounting Standards Update No. 2018-13 - Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement which improves the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement. The amendments in this Update are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after

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December 15, 2019. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. Early adoption is permitted upon issuance of this Update. We do not expect the adoption of this ASU to have a material effect on our consolidated financial statements.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective on November 5, 2018. We adopted this release in the third quarter of 2018.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

Research and Development Expenses

Research and development expenses decreased by $6.2 million to $4.9 million for the year ended December 31, 2018 from $11.1 million for the year ended December 31, 2017. The decrease in research and development expenses for the year ended December 31, 2018 is attributable to a decrease in compensation related expenses and stock compensation expenses of $2.2 million and $0.8 million respectively, driven by the restructuring activities from 2017, a decrease in consulting and clinical trial costs of $0.9 million and $0.5 million respectively, due to The INSPIRE Study being placed on hold, a decrease in facilities and rent expense of $0.6 million as a result of the Cambridge Lease Assignment (as defined below), a decrease in administrative and operating costs of $0.4 million as a result of the cost cutting measures we initiated in 2018, a decrease in legal fees of $0.3 million, a decrease in depreciation expense of $0.2 million, a decrease in recruiting costs of $0.2 million, and a decrease in travel related expenses of $0.1 million.

General and Administrative Expenses

General and administrative expenses decreased by $5.7 million to $7.8 million for the year ended December 31, 2018 from $13.5 million for year ended December 31, 2017. This decrease in general and administrative expenses is attributable to a decrease in stock compensation and compensation related expenses of $2.6 million and $1.5 million respectively, driven by the restructuring activities from 2017, a decrease in facilities and rent expenses of $0.8 million as a result of the Cambridge Lease Assignment, a decrease in legal fees of $0.7 million, a decrease in administrative and operating costs of $0.3 million, a decrease in travel related expenses of $0.1 million and a decrease in depreciation expense of $0.1 million. These decreases were partially offset by increases in consulting and recruiting expenses of $0.2 million each.

Interest Income / (Expense)

Interest income increased by $91 thousand to $206 thousand for the year ended December 31, 2018 from $115 thousand for the year ended December 31, 2017. This increase is due to a higher average balance of funds in our cash and cash equivalents balances in 2018 and a decrease in interest expense due to lower average borrowings in 2018.

Derivatives Gain / (Loss)

Derivatives loss for the year ended December 31, 2018 was $12.2 million compared to a loss of $2.3 million for the year ended December 31, 2017. The loss of $12.2 million for the year ended December 31, 2018 can be attributed to the issuance of the liability classified warrants in 2018 and the subsequent change in fair value through the date of warrant exercises or reclassification to equity.

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Other Income

Other income for the year ended December 31, 2018 was $1.3 million primarily due to a settlement agreement with a former vendor. We did not generate any other income for the year ended December 2017.

Liquidity and Capital Resources

Since inception, we have devoted substantially all of our efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets, and raising capital. At December 31, 2018, our accumulated deficit was $207.3 million.

At December 31, 2018, we had total assets of $18.4 million, total liabilities of $2.3 million, and total stockholders' equity of $16.1 million. We recorded a net loss of $23.4 million for the year ended December 31, 2018. 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. The financing we closed in June 2018, described in more detail below, provided necessary funding to fund operations into the first quarter of 2020. 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. 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. Based on these factors, management determined that there is substantial doubt regarding the Company's ability to continue as a going concern.

Financings Transactions

In June 2018, we closed an underwritten public offering of an aggregate of 1,378,400 Common Units, at an offering price of $2.00 each, each comprised of 1 share of our common stock, par value $0.00001 per share and 1 Series A warrant to purchase 1 share of common stock. The public offering also included 6,242,811 pre-funded units at an offering price of $1.99 each, each comprised of 1 pre-funded Series B Warrant and 1 Series A warrant to purchase 1 share of common stock. Each Series A warrant has an exercise price of $2.00 per share, exercisable immediately from the date of issuance and expires 5 years from the date of issuance. Each Series B warrant has an exercise price of $0.01 per share, exercisable immediately from the date of issuance and expires 20 years from the date of issuance. The net proceeds to us, after deducting the underwriting discounts and commissions and other offering expenses, were

$13.5 million. During the year ended December 31, 2018, we issued an aggregate of 6,242,811 shares of common stock upon the exercise of Series B warrants for aggregate proceeds of $62 thousand. There are no outstanding Series B warrants as of December 31, 2018. During the year ended December 31, 2018, we issued an aggregate of 34,500 shares of common stock upon the exercise of Series A warrants for aggregate proceeds of $69 thousand.

In September 2018, we entered into an Amendment to Warrant Agency Agreement and Warrants, or the Ladenburg Warrant Amendment, with Continental Stock Transfer & Trust Company, or Continental, that amends the Warrant Agency Agreement, by and between us and Continental, as Warrant Agent, dated June 25, 2018, and the Series A Common Stock Purchase Warrant, and the Series B Pre-Funded Common Stock Purchase Warrant both dated June 25, 2018, and we refer to the Series A and Series B Warrant collectively as the 2018 Warrants. See Notes 9, 10 and 12 to our Consolidated Financial Statements for more information about the Ladenburg Warrant Amendment.

In January 2018, we entered into a purchase and a registration rights agreement with Lincoln Park Capital Fund, LLC, which we refer to as Lincoln Park, under which we have the right to sell up to $15 million in shares of our common stock to Lincoln Park over a 24-month period, subject to certain limitations and conditions set forth in the purchase agreement and registration rights agreement. On May 30, 2018 at our Annual Meeting of Stockholders, our stockholders approved an increase to the number of shares of common stock available for issuance and sale by us to Lincoln Park, including our prior issuances and sales of shares of common stock to Lincoln Park since January 2018, up to 1,200,000 shares of common stock. In accordance with the terms of the purchase agreement, at the time we signed the purchase agreement and the registration rights agreement, we issued 17,192 shares to Lincoln Park as consideration for

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its commitment to purchase shares of our common stock under the purchase agreement and recorded $627 thousand in deferred offering costs of which the full amount was capitalized into additional paid-in capital as of December 31, 2018. During the year ended December 31, 2018 we sold an aggregate of 256,804 shares to Lincoln Park, for aggregate proceeds of $3.1 million net of issuance costs.

On August 10, 2017, we entered into exchange agreements with certain holders of warrants dated May 9, 2014, which we refer to as the 2014 Warrants. Pursuant to the exchange agreements, certain of the 2014 Warrants were exchanged for shares of common stock equivalent to 3.5 times the number of shares of common stock issuable to such holders upon exercise, at the $96.75 exercise price under the warrants as of the date of the exchanges. We issued an aggregate of 80,857 shares of common stock to the participating warrant holders in exchange for their 2014 Warrants for the purchase of an aggregate of 23,102 shares of common stock. We subsequently cancelled and terminated those 2014 Warrants exchanged in this transaction. Following the warrant exchange, there were additional 2014 Warrants to purchase shares of common stock that remained outstanding, which we refer to as the Outstanding 2014 Warrants. As a result of our issuance of common stock in exchange for certain of the 2014 Warrants, the exercise price of the Outstanding 2014 Warrants was adjusted downwards from $96.75 per share to $20.75 per share and additional warrants were issued such that the Outstanding 2014 Warrants were exercisable for an aggregate of 1,941 shares of common stock. The Outstanding 2014 Warrants were subject to further adjustment in the event of sales of our common stock at a price per share less than the exercise price of the Outstanding 2014 Warrants then in effect (or securities convertible or exercisable into common stock at a conversion or exercise price less than the exercise price then in effect). In the fourth quarter of 2017, we entered into warrant cancellation agreements with certain remaining holders of the Outstanding 2014 Warrants to cancel and terminate such warrants for total cash consideration of $40 thousand. During the year ended December 31, 2018, we entered into warrant cancellation agreements with certain remaining holders of the Outstanding 2014 Warrants to cancel and terminate such warrants for total cash consideration of $14 thousand. As of December 31, 2018, the remaining Outstanding 2014 Warrants were exercisable for an aggregate of 307 shares of common stock.

In May 2018, we entered into the Warrant Amendment, (as defined in Note 10 in the accompanying notes to our Consolidated Financial Statements in Item 8 of this report), which removed provisions that had previously precluded equity classification treatment of the 2014 Warrants on our balance sheet. The fair value of the amended 2014 Warrants was re-measured immediately prior to the date of amendment with changes in fair value recorded as a loss of $1 thousand in the consolidated statement of operations and $1 thousand was reclassified to equity.

Facility Changes

In May 2018, we assigned our commercial lease for 26,342 square feet in Cambridge, Massachusetts to a third party, who assumed from us all of our remaining rights and obligations under the lease (the “Cambridge Lease Assignment”). Concurrently with the lease assignment, we entered into a sublease for 5,104 square feet of the originally leased space. The sublease ends on October 31, 2023 and contains rent holidays and rent escalation clauses. In order to obtain the consent of our lender for these facility changes and the sale of certain assets, we repaid $300 thousand of principal on our loan and recorded an impairment charge of $48 thousand on abandoned fixed assets and leasehold improvements. For more information, see Note 7 and Note 15 to the notes to our Consolidated Financial Statements in Item 8 of this report.

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 estimated savings of approximately $7.3 million in annual operating expenses, with one-time severance and related costs of $857 thousand. Of these one-time severance and related costs, approximately $509 thousand was paid through December 31, 2017 and the remaining $348 thousand was paid as of December 31, 2018.

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.

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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, 2018 was $12.3 million compared to $19.7 million for the year ended December 31, 2017. The change in net cash used in operating activities for the year ended December 31, 2018 as compared to the same period in the prior year was primarily due to an decrease in our net loss of $3.3 million, an increase in the change in derivative loss of $10 million, a decrease in share-based compensation expense of $3.5 million, a decrease in the change in other assets of $1.3 million, a gain on lease assignment of $0.6 million and a decrease in depreciation and amortization expense of $0.3 million.

Net cash used in investing activities for the year ended December 31, 2018 was $65 thousand attributable to purchases of capital equipment. This compares to net cash from in investing activities for the year ended December 31, 2017 of $11.5 million attributable to sales of marketable securities of $19.8 million offset by purchases of marketable securities and capital equipment of $8.3 million and $65 thousand respectively.

Net cash provided by financing activities for the year ended December 31, 2018 was $15.9 million consisting primarily of $16.5 million in proceeds from the issuance of common stock associated with the June 2018 underwritten public offering and the Lincoln Park financing agreement, $0.1 million in proceeds from exercise of warrants offset by $0.8 million in loan repayments and $14 thousand for the repurchase of warrants. This compares to net cash of $0.4 million used in financing activities 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 thousand. These proceeds were offset by the repayment of loan principal of $423 thousand and payment of $40 thousand 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.

Inflation and Changing Prices

We do not believe that inflation has had, or will have, a material impact on our operating costs and earnings.

Commitments

See Note 15, “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

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information under this item.

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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 25 reverse stock split of the Company's common stock effected on April 16, 2018.

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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

We have audited the accompanying consolidated balance sheets of InVivo Therapeutics Holdings Corp. and Subsidiary (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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 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

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits 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. We believe that our audits provide a reasonable basis for our opinion.

/s/ RSM US LLP

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

Boston, Massachusetts

April 1, 2019

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InVivo Therapeutics Holdings Corp.

Consolidated Balance Sheets

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

	December 31, 2018	2017
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 16,660	$ 12,910
Restricted cash	4	361
Prepaid expenses and other current assets	461	535
Total current assets	17,125	13,806
Property, equipment and leasehold improvements, net	100	157
Restricted cash	110	—
Other assets	1,042	82
Total assets	$ 18,377	$ 14,045
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 815	$ 988
Loan payable, current portion	100	452
Derivative warrant liability	—	4
Deferred rent, current portion	—	30
Accrued expenses	1,290	1,638
Total current liabilities	2,205	3,112
Loan payable, net of current portion	—	400
Deferred rent, net of current portion	—	367
Other liabilities	61	56
Total liabilities	2,266	3,935
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Common stock, $0.00001 par value, authorized 25,000,000 shares; 9,309,255 shares issued and outstanding at December 31, 2018; 1,370,992 shares issued and outstanding at December 31, 2017	1	1
Additional paid-in capital	223,440	194,016
Accumulated deficit	(207,330)	(183,907)
Total stockholders' equity	16,111	10,110
Total liabilities and stockholders' equity	$ 18,377	$ 14,045

See notes to the consolidated financial statements.

(Reflects the retrospective application of the 1-for-25 reverse stock split effective April 16, 2018)

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InVivo Therapeutics Holdings Corp.

Consolidated Statements of Operations and Comprehensive Loss

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

	Year Ended December 31,	
	2018	2017
Operating expenses:		
Research and development	$ 4,931	$ 11,083
General and administrative	7,836	13,510
Total operating expenses	12,767	24,593
Operating loss	(12,767)	(24,593)
Other income / (expense):		
Interest income / (expense), net	206	115
Other income	1,303	—
Derivatives (loss)	(12,165)	(2,267)
Other income / (expense), net	(10,656)	(2,152)
Net loss	$ (23,423)	$ (26,745)
Net loss per share, basic and diluted	$ (4.69)	$ (20.29)
Weighted average number of common shares outstanding, basic and diluted	4,990,089	1,318,003
Other comprehensive loss:		
Net loss	$ (23,423)	$ (26,745)
Other comprehensive loss:		
Unrealized gain / (loss) on marketable securities	—	—
Comprehensive loss	$ (23,423)	$ (26,745)

See notes to the consolidated financial statements.

(Reflects the retrospective application of the 1-for-25 reverse stock split effective April 16, 2018)

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InVivo Therapeutics Holdings Corp.

Consolidated Statements of Changes in Stockholders' Equity

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

	Common Stock Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance as of December 31, 2016	1,281,763	$ 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	80,857	—	3,537	—	3,537
Issuance of common stock for services	14	—	—	—	—
Issuance of common stock upon exercise of warrants	139	—	3	—	3
Issuance of common stock upon exercise of stock options	3,576	—	26	—	26
Issuance of common stock under ESPP	710	—	51	—	51
Issuance of common stock to 401(k) plan	3,933	—	183	—	183
Net loss	—	—	—	(26,745)	(26,745)
Balance as of December 31, 2017	1,370,992	1	194,016	(183,907)	10,110
Share-based compensation expense	—		618		618
Fair value of derivative warrant liability reclassified to additional paid-in capital	—	—	25,327	—	25,327
Issuance of common stock upon vesting of restricted stock units	4,250	—	—	—	—
Issuance of common stock upon exercise of warrants	6,277,311	—	131	—	131
Issuance of common stock under ESPP	1,133	—	4	—	4
Fractional shares issued due to reverse stock split	2,733	—	—	—	—
Issuance of common stock to 401(k) plan	440	—	6	—	6
Issuance of common stock in public offering	1,652,396	—	3,338	—	3,338
Net Loss	—	—	—	(23,423)	(23,423)
Balance as of December 31, 2018	9,309,255	$ 1	$ 223,440	$ (207,330)	$ 16,111

See notes to the consolidated financial statements.

(Reflects the retrospective application of the 1-for-25 reverse stock split effective April 16, 2018)

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InVivo Therapeutics Holdings Corp.

Consolidated Statements of Cash Flows

(In thousands)

	Years Ended December 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	$ (23,423)	$ (26,745)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	91	395
Loss on impairment of fixed assets	48	41
Derivatives loss	12,165	2,267
Non-cash interest expense	—	5
Common stock issued to 401(k) plan	6	183
Gain on lease assignment	(603)	—
Share-based compensation expense	618	4,106
Non-cash investment (income) expense, net	3	—
Changes in operating assets and liabilities:		
Prepaid expenses	77	(89)
Other assets	(985)	321
Accounts payable	(173)	(23)
Accrued expenses and other liabilities	(136)	(144)
Net cash used in operating activities	(12,312)	(19,683)
Cash flows from investing activities:		
Purchases of marketable securities	—	(8,256)
Sales of marketable securities	—	19,833
Purchases of property and equipment	(65)	(65)
Net cash (used in) provided by investing activities	(65)	11,512
Cash flows from financing activities:		
Proceeds from exercise of stock options	—	26
Proceeds from issuance of stock under ESPP	4	51
Proceeds from exercise of warrants	131	3
Repayment of loan payable	(752)	(423)
Repurchase of warrants	(14)	(40)
Proceeds from issuance of common stock and warrants, net of commissions and issuance costs	16,511	—
Net cash provided by (used in) financing activities	15,880	(383)
Increase (decrease) in cash and cash equivalents and restricted cash	3,503	(8,554)
Cash, cash equivalents and restricted cash at beginning of period	13,271	21,825
Cash, cash equivalents and restricted cash at end of period	$ 16,774	$ 13,271

Supplemental disclosure of cash flow information and non-cash investing and financing activities:		
Cash paid for interest	$ 44	$ 71
Cash paid for taxes	$ 18	$ —
Non-cash issuance of common stock for warrants	$ 287	$ 3,537
Reclassification of derivative warrant liability to additional paid-in capital	$ 25,327	$ —

See notes to the consolidated financial statements.

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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, 2018, the Company has consolidated cash and cash equivalents of $16.7 million. 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, 2018 were prepared under the assumption that the Company will continue as a going concern. At December 31, 2018, the Company had cash and cash equivalents of $16.7 million. Given the Company's development plans, the Company estimates cash resources will be sufficient to fund its operations into the first quarter of 2020. 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

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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 3 months from date of purchase to be cash equivalents.

At December 31, 2018 and 2017, cash equivalents were comprised of money market funds and other short-term investments.

Cash and cash equivalents consist of the following:

(In thousands)	December 31, 2018	December 31, 2017
Cash	$ (83)	$ 23
Money market funds	16,743	12,887
Total cash and cash equivalents	$ 16,660	$ 12,910

Restricted cash

Restricted cash as of December 31, 2018 was $114 thousand and included a $50 thousand security deposit related to the Company’s credit card account, $4 thousand related to 401(k) reserve account and a $60 thousand standby letter of credit in favor of a landlord (see Note 15).

Restricted cash as of December 31, 2017 was $361 thousand and included a $50 thousand security deposit related to the Company's credit card account and a $311 thousand standby letter of credit in favor of a landlord (see Note 15).

Financial instruments

The carrying amounts reported in the Company's consolidated balance sheets for cash, cash equivalents 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. Certain agreements require the Company to make pre-payments for CRO services. As of December 31, 2018, the Company had $1.3 million in

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prepayments for CRO services of which $290 thousand is included in prepaid and other current asset balance on the balance sheet and the remaining $996 thousand is included within the other long term assets balance on the balance sheet.

Concentrations of credit risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. 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 1 operating segment, which is developing and commercializing biopolymer scaffolding devices for the treatment of spinal cord injuries. As of December 31, 2018, and 2017, all of the Company’s assets were located in 1 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, 2018 or 2017. Tax years subsequent to 2014 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 reduced the US federal corporate tax rate from 35% to 21%, required companies to pay a 1-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred and created new taxes on certain foreign sourced earnings. On December 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, 2018, the Company had completed its accounting for the tax effects of enactment of the Act, including the effects on its existing deferred tax balances, and the corresponding valuation allowance and the 1-time transition tax. For the year ended December 31, 2018, the Company recognized no transition tax, remeasured deferred taxes, and its reassessment of uncertain tax positions and valuation allowances.

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 May 3, 2018, the Company assigned the Cambridge Lease (as defined in Note 15)

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to a third party who assumed all of the Company's remaining rights and obligations under the Cambridge Lease and as a result recorded an impairment charge of $48 thousand. On August 28, 2017, the Company implemented a strategic restructuring and as a result recorded an impairment charge of $41 thousand (see Note 3).

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, 2018 and 2017, the following potentially dilutive securities were not included in the computation of net loss per share because the effect would be anti-dilutive:

	December 31,	
	2018	2017
Warrants	7,673,130	86,646
Stock options	54,849	134,770
Unvested restricted stock units	10,250	20,000
Total potentially dilutive securities	7,738,229	241,416

Recent accounting pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 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

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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. Collectively, these standards are effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within each annual reporting period. The Company adopted ASU 2014-09 on January 1, 2018, and it did not have any impact on the financial position, results of operations or disclosures as the Company currently does not generate any revenue.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments - Overall (Subtopic 825-10) - Recognition and Measurement of Financial Assets and Financial Liabilities ("ASU 2016-01"). ASU 2016-01 is intended to improve the recognition and measurement of financial instruments by; requiring equity investments to be measured at fair value with changes in fair value recognized in net income: requiring public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requiring separate presentation of financial assets and financial liabilities by measurement category and form of financial asset on the balance sheet or the accompanying notes to the financial statements; eliminating the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured and amortized at cost on the balance sheet; and requiring a reporting organization to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the organization has elected to measure the liability at fair value in accordance with the fair value option for financial instruments. ASU 2016-01 is effective for annual periods and interim periods within those annual periods, beginning after December 15, 2017. The amendments should be applied by means of a cumulative-effect adjustment to the balance sheet as of the beginning of the fiscal year of adoption. The amendments related to equity securities without readily determinable fair values (including disclosure requirements) should be applied prospectively to equity investments that exist as of the date of adoption. In February 2018, the FASB issued ASU No. 2018-03 which includes technical corrections and improvements to clarify the guidance in ASU No. 2016-01. The Company adopted ASU 2016-01 on January 1, 2018 and it did not have any impact on its accounting for equity investments, fair value disclosures or other disclosure requirements.

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 FASB has subsequently issued amendments to the guidance, including the addition of an optional transition method and provided clarifications to address potential narrow-scope implementation issues. The adoption of ASU 2016-02 will result in an increase to the Company's consolidated balance sheets for right-of-use assets and lease liabilities. The Company adopted ASU 2016- 02 effective January 1, 2019 and elected the optional transition method for adoption. The Company also took advantage of the transition package of practical expedients permitted within ASU 2016-02, which among other things, allowed it to carryforward historical lease classifications. The Company also elected to keep leases with an initial term of 12 months or less off of the balance sheet as a policy election and will recognize those lease payments in the consolidated statements of operations on a straight-line basis over the lease term. Based on our current lease portfolio, the Company estimates that the adoption of this standard will result in approximately $1.5 million of additional assets and liabilities being reflected on our consolidated balance sheets on January 1, 2019; however, there will not be a material impact to its consolidated statement of operations or cash flows.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments (“ASU No. 2016-15”), which clarifies the classification of certain cash receipts and cash payments in the statement of cash flows, including debt prepayment or extinguishment costs, settlement of contingent consideration arising from a business combination and insurance settlement proceeds. The Company adopted ASU 2016-15 on January 1, 2018, and it did not result in any changes to the presentation of amounts shown on the Company’s consolidated statements of cash flows for all periods presented.

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (A Consensus of the FASB Emerging Issues Task Force) (“ASU No 2016-18”). The amendments in this update require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company adopted ASU No. 2016-

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18 in the first quarter of 2018 and applied the guidance retrospectively to the prior period consolidated statement of cash flows. The following table provides a reconciliation of cash, cash equivalents, and restricted cash within the statement of financial position that sum to the total of the same such amounts shown in the statement of cash flows.

(In thousands)	December 31, 2018	December 31, 2017
Cash and cash equivalents	$ 16,660	$ 12,910
Restricted cash included in current assets	4	361
Restricted cash included in other non-current assets	110	—
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 16,774	$ 13,271

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. The Company adopted ASU 2017-09 on January 1, 2018 and it did not have a material effect on the Company’s financial position, results of operations or disclosures.

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 ASU 2017-11 will not have a material impact on the financial statements.

In February 2018, the FASB issued Accounting Standards Update No. 2018-02, Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income. This update relates to the impacts of the tax legislation commonly referred to as the Tax Reform Act. The guidance permits the reclassification of certain income tax effects of the Tax Reform Act from other comprehensive income to retained earnings (stranded tax effects). The guidance also requires certain new disclosures. The guidance is effective for annual periods beginning after December 15, 2018, and interim periods within those reporting periods. Early adoption is permitted. Entities may adopt the guidance using 1 of 2 transition methods; retrospective to each period (or periods) in which the income tax effects of the Tax Reform Act related to the items remaining in other comprehensive income are recognized or at the beginning of the period of adoption. The Company is currently evaluating the impact that the guidance may have on its consolidated financial statements.

In June 2018, the FASB issued Accounting Standards Update No. 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting which is intended to reduce cost and complexity and to improve financial reporting for nonemployee share-based payments. The amendment is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company does not expect the adoption of this Accounting Standard to have a material effect on its consolidated financial statements.

In July 2018, the FASB issued Accounting Standards Update No. 2018-09, Codification Improvements which clarifies, corrects errors in, and makes improvements to several Codification Topics, including to:

- Clarify when excess tax benefits should be recognized for share-based compensation awards
- Remove inconsistent guidance in income tax accounting for business combinations
- Clarify the circumstances when derivatives may be offset
- Clarify the measurement of liability or equity-classified financial instruments when an identical asset is

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held as an asset
- Allow portfolios of financial instruments and nonfinancial instruments accounted for as derivatives to use the portfolio exception to valuation

The transition and effective date guidance is based on the facts and circumstances of each amendment. Some of the amendments in this Update do not require transition guidance and will be effective upon issuance of this Update. However, many of the amendments in this Update do have transition guidance with effective dates for annual periods beginning after December 15, 2018. The Company is currently evaluating the impact that the guidance may have on its consolidated financial statements.

In August 2018, the FASB issued Accounting Standards Update No. 2018-13 - Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement which improves the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement. The amendments in this Update are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. Early adoption is permitted upon issuance of this Update. The Company does not expect the adoption of this Accounting Standard to have a material effect on its consolidated financial statements.

In August 2018, the SEC adopted the final rule under SEC Release No. 33-10532, Disclosure Update and Simplification, amending certain disclosure requirements that were redundant, duplicative, overlapping, outdated or superseded. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The analysis should present a reconciliation of the beginning balance to the ending balance of each period for which a statement of comprehensive income is required to be filed. This final rule is effective on November 5, 2018. The Company adopted this release in the third quarter of 2018.

3. PROPERTY AND EQUIPMENT

Property and equipment, net consisted of the following:

(In thousands)	2018	2017
Computer software and hardware	$ 131	$ 241
Research and lab equipment	508	508

Leasehold improvements	66	431
Office equipment	—	796
Property and equipment	705	1,976
Less accumulated depreciation and amortization	(605)	(1,819)
Property and equipment, net	$ 100	$ 157

Depreciation expense for the years ended December 31, 2018 and 2017, was $74 thousand, and $377 thousand, respectively. Maintenance and repairs are charged to expense as incurred and any additions or improvements are capitalized.

On May 3, 2018, the Company assigned the Cambridge Lease to a third party who assumed all of the Company's remaining rights and obligations under the Cambridge Lease and as a result wrote off $1.3 million of fully depreciated assets and also recorded an impairment loss of $48 thousand related to certain fixed assets in connection with the reassignment.

On August 28, 2017, the Company implemented a strategic restructuring and as a result wrote off $1.8 million of fully depreciated assets and also recorded an impairment loss of $41 thousand related to certain fixed assets in connection with the restructuring.

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4. INTANGIBLE ASSETS

Intangible assets, included in “other assets,” consisted of patent licensing fees paid to license intellectual property (see Note 14). The Company is amortizing the license fee as a research and development expense over the 15– year term of the license.

(In thousands)	2018	2017
Patent licensing fee	$ 200	$ 200
Accumulated amortization	(156)	(139)
Intangible assets, net	$ 44	$ 61

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

5. ACCRUED EXPENSES

Accrued expenses consisted of the following:

(In thousands)	December 31, 2018	December 31, 2017
Severance and restructuring	$ 517	$ 1,160
Compensation	489	196
Clinical	73	52
Legal	35	68
Other accrued expenses	176	162
Total accrued expenses	$ 1,290	$ 1,638

6. FAIR VALUES OF ASSETS AND LIABILITIES

The Company groups its assets and liabilities generally measured at fair value in 3 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.

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

	At December 31, 2018			
(In thousands)	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	$ 16,743	$ —	$ —	$ 16,743

	At December 31, 2017			
(In thousands)	Level 1	Level 2	Level 3	Fair Value
Cash equivalents	$ 12,887	$ —	$ —	$ 12,887
Derivative warrant liability	$ —	$ 4	$ —	$ 4

7. 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 $2.0 million line of credit from the Commonwealth of Massachusetts’s Emerging Technology fund, with $200 thousand 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 30 months, commencing on November 1, 2012, and then equal interest and principal payments over the next 54 months, until the final maturity of the loan on October 5, 2019. Commencing on May 1, 2015, equal monthly principal payments of $41 thousand are due until loan maturity.

In May 2018, in order to obtain the consent of MassDev for facility changes, including the assignment of the Cambridge Lease, and the sale of certain assets, the Company paid down $300 thousand of principal on the MassDev loan. As of December 31, 2018, $100 thousand in principal payments will be due in the next 3 months. In October 2012, as part of the agreement, the Company issued MassDev a warrant for the purchase of 362 shares of the Company’s common stock of which 243 shares remaining outstanding at December 31, 2018. The warrant has a 7-year term and is exercisable at $166 per share. The fair value of the warrant was determined to be $32 thousand and is being amortized through interest expense over the life of the note. For the years ended December 31, 2018 and 2017, the expense was $7 thousand and $5 thousand respectively, 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 $43 thousand and $71 thousand for the years ended December 31, 2018 and 2017, respectively.

At December 31, loans payable consisted of the following:

	December 31,	
(In thousands)	2018	2017
MassDev Loan	$ 100	$ 852
Less: current portion	(100)	(452)
Notes Payable long-term portion	$ —	$ 400

8. 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, 2018, the Company had U.S. federal and Massachusetts net operating loss carryforwards of $128.9 million and $120.8 million, respectively, of which $117.3 million of federal carryforwards will expire in varying amounts beginning in 2026 and $11.6 million carry forward indefinitely. 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 $1.2 million and $258 thousand respectively, at December 31, 2018, which will begin to expire in 2022 unless previously utilized.

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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 1-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, 2018, the Company has completed its accounting for the tax effects of enactment of the Act, including the effects on our existing deferred tax balances, the corresponding valuation allowance and the 1- time transition tax. For the year ended December 31, 2018, the Company recognized no transition tax, have remeasured deferred taxes, and our reassessment of uncertain tax positions and valuation allowances.

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

	December 31,	
(In thousands)	2018	2017
Net operating loss carryforward	$ 34,846	$ 31,533
Research and development credit carryforward	1,390	1,173
Stock-based compensation	2,300	2,828
Depreciation and amortization	11	71
Accrued expenses	136	357
Charitable contributions	—	27
Subtotal	38,683	35,989
Valuation allowance	(38,683)	(35,989)
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 thousand 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, 2018 and 2017, the valuation allowance increased by $2.7 million and decreased by $7.9 million, respectively.

The Company has no uncertain tax positions at December 31, 2018 and 2017 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 12 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,			
	2018		2017	
Statutory rate	(21.0)	%	(34.0)	%
State taxes, net of benefit	(2.9)	%	(4.7)	%
Permanent differences:				
Derivative losses	10.9	%	2.9	%
Other	0.4	%	1.1	%
Research and development tax credit	(0.8)	%	(0.2)	%
Other	1.9	%	1.4	%
Adoption of ASU 2016-09	—	%	7.4	%
Increase / (decrease) in valuation reserve	11.5	%	(32.0)	%
Change in federal tax rate	—	%	58.1	%
Effective tax rate	0.0	%	0.0	%

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9. COMMON STOCK

In May 2018, the Company's stockholders approved an amendment to the Company's Articles of Incorporation to increase the number of shares of authorized common stock from 4,000,000 to 25,000,000 shares of common stock. As of December 31, 2018, and 2017, 9,309,255, and 1,370,992 shares were issued and outstanding respectively.

In June 2018, the Company closed an underwritten public offering of an aggregate of 1,378,400 Common Units, at an offering price of $2.00 each, each comprised of 1 share of its common stock, par value $0.00001 per share and 1 Series A warrant to purchase 1 share of common stock. The public offering also included 6,242,811 pre-funded units at an offering price of $1.99 each, each comprised of 1 pre-funded Series B Warrant and 1 Series A warrant to purchase 1 share of common stock. Each Series A warrant has an exercise price of $2.00 per share, exercisable immediately from the date of issuance and expires 5 years from the date of issuance. Each Series B warrant has an exercise price of $0.01 per share, exercisable immediately from the date of issuance and expires 20 years from the date of issuance. The net proceeds to the Company, after deducting the underwriting discounts and commissions and other offering expenses, were $13.5 million. In September 2018, the Company entered into an Amendment to Warrant Agency Agreement and Warrants (the "Ladenburg Warrant Amendment") with Continental Stock Transfer & Trust Company ("Continental") that amends the Warrant Agency Agreement, by and between the Company and Continental, as Warrant Agent, dated June 25, 2018, and the Series A Common Stock Purchase Warrant, and the Series B Pre-Funded Common Stock Purchase Warrant both dated June 25, 2018 (the Series A and Series B Warrant, collectively the "2018 Warrants"). The Ladenburg Warrant Amendment adds a provision to each of the warrants that allows the Company or a successor entity whose stock is not listed on a trading market to, in connection with a Fundamental Transaction (as such term is defined in the 2018 Warrants) that is not within the Company's control, purchase the warrant from the holder, at the holder's option, by paying the same form of consideration in the same proportion that is offered to the holders of the Company's common stock in connection with the Fundamental Transaction, including cash, stock, any combination thereof and any choice of consideration thereof, in an amount equal to the Black-Sholes Value of the remaining unexercised portion of the Warrant on the consummation date of the Fundamental Transaction. As a result of the amendment, the Company reassessed the warrant classification and concluded that the warrants qualified for equity classification. The fair value of the amended 2018 Warrants was re-measured immediately prior to the date of the Ladenburg Warrant Amendment with changes in fair value recorded as a loss of $764 thousand in the Company's consolidated statement of operations and $14.7 million was reclassified to equity. During the year ended December 31, 2018, the Company issued an aggregate of 6,242,811 and 34,500 shares of common stock upon the exercise of Series B and Series A warrants respectively for aggregate proceeds of $131 thousand. The Company reclassified $10.6 million from derivative warrant liability to additional paid-in capital and recorded a derivative loss of $1.2 million in connection with the warrant exercises.

In January 2018, the Company entered into a purchase and a registration rights agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"), under which it has the right to sell up to $15 million, in shares of its common stock, $0.00001 par value per share, to Lincoln Park over a 24 month period, subject to certain limitations and conditions set forth in the purchase agreement and registration rights agreement. On May 30, 2018 the Company's stockholders approved to increase the issuance and sale by the Company to Lincoln Park, including the Company's prior issuances and sales of shares of common stock to Lincoln Park since January 2018, of up to 1,200,000 shares of common stock. In accordance with the terms of the purchase agreement, at the time the Company signed the purchase agreement and the registration rights agreement, it issued 17,192 shares to Lincoln Park as consideration for its commitment to

purchase shares of the Company's common stock under the purchase agreement and recorded $627 thousand in deferred offering costs of which the full amount was capitalized into additional paid-in capital as of December 31, 2018. During the year ended December 31, 2018 the Company sold an aggregate of 256,804 shares to Lincoln Park, for aggregate proceeds of $3.1 million net of issuance costs.

In May 2018, the Company's Board of Directors approved to increase the number of shares of Common Stock reserved under the 401(k) Plan by 4,000 shares, bringing the aggregate number of shares of Common Stock eligible for distribution pursuant to the 401(k) Plan as of that date to 4,100 shares. In the second quarter of 2018, the Company revised its 401(k) matching policy to move from share matching to cash-based matching. During the year ended December 31, 2018, the Company issued an aggregate of 440 shares of common stock with a fair value of $6 thousand to the Company's 401(k) plan as a matching contribution. The Company contributed $44 thousand in matching cash contributions to employee 401(k) accounts during the year ended December 31, 2018.

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During the year ended December 31, 2018, the Company issued an aggregate of 1,133 shares of common stock under the Company's Employee Stock Purchase Plan (the "ESPP") and received cash proceeds of $4 thousand.

As part of the adjustment to reflect the Company's 1-for-25 reverse stock split on its common stock on April 16, 2018, the Company issued 2,733 shares of common stock to account for the fractional roundup of shareholders.

During the year ended December 31, 2018, the Company issued an aggregate of 4,250 shares of common stock upon vesting of restricted stock units.

During the year ended December 31, 2017, the Company issued an aggregate of 3,576 shares of common stock upon the exercise of stock options and received cash proceeds from such exercises of $26 thousand.

During the year ended December 31, 2017, the Company issued an aggregate of 139 shares of common stock upon the exercise of warrants and received cash proceeds from such exercises of $3 thousand.

During the year ended December 31, 2017, the Company issued an aggregate of 3,933 shares of common stock with a fair value of $183 thousand to the Company's 401(k) plan as a matching contribution.

During the year ended December 31, 2017, the Company issued an aggregate of 710 shares of common stock under the ESPP and received cash proceeds of $51 thousand.

During the year ended December 31, 2017, the Company issued an aggregate of 80,857 shares of common stock to certain holders of warrants, dated May 9, 2014, in exchange for their warrants to purchase an aggregate of 23,102 shares of common stock. The Company did not receive any cash proceeds from the warrant exchanges.

Common Stock Reserves

As of December 31, 2018, the Company had the following reserves established for the future issuance of common stock as follows:

Reserves for the exercise of warrants	7,673,130
Reserves for the exercise of stock options	54,849
Reserves for the vesting of restricted stock units	10,250
Total Reserves	7,738,229

10. DERIVATIVE INSTRUMENTS

The warrants issued in connection with the Company's 2018 underwritten public offering had provisions that precluded the Company from classifying them as equity instruments (See Note 12). Accordingly, these warrants had been accounted for as derivative warrant liabilities. The Company used the Black-Scholes model and assumptions that considered, 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 these warrants.

At inception, the fair value of the Series B pre-funded warrants was estimated at $11.5 million using a Black-Scholes model with the following assumptions: expected volatility of 202.51%, risk free interest rate of 2.95%, expected life of 20 years and no dividends.

At inception, the fair value of the Series A warrants was estimated at $13.7 million using a Black-Scholes model with the following assumptions: expected volatility of 202.51%, risk free interest rate of 2.75%, expected life of 5 years and no dividends.

The Company allocated $13.2 million of the net proceeds to record the relative fair value of the warrant liability, with the remaining amount of $287 thousand recorded to permanent equity. The Company subsequently recorded the fair value of the warrant liability at $25.2 million with the loss of $12 million being recorded as a derivative loss on the Company's consolidated statement of operations and comprehensive loss during the second quarter of 2018.

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In September 2018, the Company entered into the Ladenburg Warrant Amendment. As a result of the amendment, the Company reassessed the warrant classification and concluded that the warrants qualified for equity classification. The fair value of the amended 2018 Warrants was re-measured immediately prior to the date of the Ladenburg Warrant Amendment with changes in fair value recorded as a loss of $764 thousand in the Company's consolidated statement of operations and $14.7 million was reclassified to equity.

During the year ended December 31, 2018, the Company issued an aggregate of 6,242,811 shares of common stock upon the exercise of Series B warrants for aggregate proceeds of $62 thousand. There are no outstanding Series B warrants as of December 31, 2018. During the year ended December 31, 2018, the Company issued an aggregate of 34,500 shares of common stock upon the exercise of Series A warrants for aggregate proceeds of $69 thousand. The Company reclassified $10.6 million from derivative warrant liability to additional paid-in capital and recorded a derivative loss of $1.2 million in connection with the warrant exercises.

The 2014 Warrants issued in connection with the Company's May 2014 public offering had anti-dilution protection provisions and, under certain conditions, required the Company to automatically reprice the 2014 Warrants (See Note 12). Accordingly, the 2014 Warrants had been accounted for as derivative warrant liabilities. Through the date of the warrant exchange (see Note 12), the Company used the Binomial Lattice option pricing model and assumptions that considered, 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 2014 Warrants considered to be derivative instruments.

In May 2018, the Company entered into the Warrant Amendment (as defined below), which removed provisions that had previously precluded equity classification treatment of the 2014 Warrants on the Company's balance sheets. The fair value of the amended 2014 Warrants was re-measured immediately prior to the date of amendment with changes in fair value recorded as a loss of $1 thousand in the Company's consolidated statement of operations and $1 thousand was reclassified to equity.

As of December 31, 2018, the Company did not have any liability classified warrants. As of December 31, 2017, the derivative warrant liability was insignificant and was included as a derivative warrant liability in current liabilities on the balance sheet. Changes in the fair value of the derivative financial instruments were recognized in the Company's consolidated statement of operations as a derivative gain or loss.

The assumptions used principally in determining the fair value of the 2014 Warrants as of December 31, 2017 were as follows:

	2014 Warrants December 31, 2017
Risk-free interest rate	1.91 %

Expected dividend yield	—	%
Contractual term	1.35	years
Expected volatility	82.37	%

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

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The table below presents the changes in derivative warrant liability during years ended December 31, 2018 and 2017:

	Year Ended December 31,	
(In thousands)	2018	2017
Balance at beginning of year	$ 4	$ 1,314
Issuance of new warrants	13,172	—
Reduction in derivative liability due to exercise of warrants	(10,620)	—
Reclassification of fair value of derivative liabilities to equity on amendment of warrant agreements	(14,707)	—
Increase in derivative liability prior to warrant exchange	—	3,029
Reduction in derivative liability due to warrant exchange	—	(3,537)
Repurchase of warrants	(14)	(40)
Increase (decrease) in the fair value of warrants	12,165	(762)
Balance at end of year	$ —	$ 4

11. 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"). The 2007 Plan provided that the Company's Board of Directors (or committees and/or executive officers delegated by the Board of Directors) could grant incentive and nonqualified stock options to the Company's employees, officers, directors, consultants and advisors.

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.

Upon approval of the 2015 Plan by the Company's shareholders on June 16, 2015, the 2010 Plan was terminated and no additional shares or share awards have been subsequently granted under the 2010 Plan. As of December 31, 2018, the total number of shares available to be issued under the 2015 Plan was 188,552 shares, consisting of 160,000 shares

initially authorized under the 2015 Plan shares plus the 12,894 shares that remained available for grant under the 2010 Plan at the time of its termination adjusted for cumulative cancellations, forfeitures and issuances from the 2010 Plan and 2015 Plan.

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 7,500 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) 2,000 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 50,000 shares. As of December 31, 2018, there were 7,923 shares reserved for issuance under the ESPP.

The 2015 ESPP is considered a compensatory plan with the related compensation cost recognized over each respective 6 month offering period. As of December 31, 2018, approximately $1 thousand of employee payroll deductions had been withheld since July 1, 2018, 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

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December 31, 2018 and 2017 was $2 thousand and $14 thousand, respectively, and is included in stock-based compensation expense. In January 2019, 1,065 shares that were purchased as of December 31, 2018 were issued under the ESPP.

Share based compensation

For the years ended December 31, 2018 and 2017, the Company recorded stock based compensation expense of $618 thousand and $4.1 million, 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, 2018	December 31, 2017
Risk-free interest rate	2.45 - 2.88%	1.69 - 2.36%
Expected dividend yield	0%	0%
Expected term (employee grants)	5.62 Years	6.22 Years
Expected volatility	104%	104%

A summary of option activity as of December 31, 2018 and 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	127,752	$ 188.00	6.93	$ 571
Granted	57,579	$ 98.50		
Cancelled/Forfeited	(46,985)	$ 160.00		
Exercised	(3,576)	$ 7.25		
Outstanding at December 31, 2017	134,770	$ 164.29	7.14	$ 22
Granted	15,524	$ 4.97		
Expired	(5,334)	$ 173.13		
Cancelled/Forfeited	(90,111)	$ 175.00		
Outstanding at December 31, 2018	54,849	$ 100.83	7.32	$ —
Vested at December 31, 2018	32,522	$ 147.84	5.98	$ —

The weighted average grant date fair value of options granted during the years ended December 31, 2018 and 2017 was $3.82 and $2.54 per share, respectively. The total fair value of options that vested in years ended December 31, 2018 and 2017, was $952 thousand and $3.8 million respectively. As of December 31, 2018, there was $253 thousand 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 remaining weighted-average period of 1.99 years at December 31, 2018.

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Restricted Stock Units

The following table summarizes the restricted stock unit ("RSU") activity under the 2015 Equity Incentive Plan for the years ended December 31, 2018 and 2017:

	Number of Grants	Weighted-Average Grant Date Fair Value
Unvested balance at December 31, 2016	—	$ —
Granted	23,800	26.50
Vested/Released	—	$ —
Forfeited	(3,800)	$ 31.25
Unvested balance at December 31, 2017	20,000	$ 25.70
Granted	—	—
Vested/Released	(4,250)	$ 24.72
Forfeited	(5,500)	$ 31.25
Unvested balance at December 31, 2018	10,250	$ 23.13

For the year ended December 31, 2018, the Company recorded stock-based compensation expense of $88 thousand related to the time-based RSUs. As of December 31, 2018, total unrecognized compensation expense related to non-vested RSUs amounted to $223 thousand which the Company expects to recognize over a remaining weighted-average period of 2.68 years. All the RSU's that remain unvested and outstanding at December 31, 2018 are subject to time-based vesting.

12. WARRANTS

The following table presents information about warrants to purchase common stock issued and outstanding at December 31, 2018:

Year Issued	Classification	Number of Warrants	Exercise Price	Date of Expiration
2012	Equity	243	$ 166.00	10/5/2019
2014	Equity	307	$ 11.75	5/9/2021
2016	Equity	85,869	$ 250.00	3/18/2021
2018	Equity	7,586,711	$ 2.00	6/25/2023
Total		7,673,130		

Weighted average exercise price	$ 4.78	
Weighted average life in years		4.46

In June 2018, the Company closed an underwritten public offering of an aggregate of 1,378,400 Common Units, at an offering price of $2.00 each, each comprised of 1 share of the Company's common stock, par value $0.00001 per share and 1 Series A warrant to purchase 1 share of common stock. The public offering also included 6,242,811 pre-funded units at an offering price of $1.99 each, each comprised of 1 pre-funded Series B Warrant, and 1 Series A warrant to purchase 1 share of common stock. Each Series A warrant has an exercise price of $2.00 per share, is exercisable immediately and expires 5 years from the date of issuance. Each Series B warrant has an exercise price of $0.01 per share, is exercisable immediately and will expire 20 years from the date of issuance (see Note 10). The net proceeds to the Company, after deducting the underwriting discounts and commissions and other offering expenses, were $13.5 million.

At inception the 2014 Warrants and 2018 Warrants had provisions that precluded equity classification. Upon amendment, the Company assessed whether the warrants required accounting as derivatives and determined that the warrants were (1) indexed to the Company's own stock and (2) classified in stockholders' equity in accordance with FASB Accounting Standards Codification Topic 815, Derivatives and Hedging. As such, the Company concluded that the warrants meet the scope exception for determining whether the instruments require accounting as derivatives and accordingly are classified in stockholders' equity. See below for a further description of the warrant amendments.

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Warrant Exchange

On August 10, 2017, the Company entered into exchange agreements with certain holders of the warrants, dated May 9, 2014, to exchange such warrants for shares of common stock equivalent to 3.5 times the number of shares of common stock issuable to such holders at the $96.75 exercise price under the warrants as of the date of the exchanges. The Company issued an aggregate of 80,857 shares of common stock to the warrant holders in exchange for their warrants to purchase an aggregate of 23,102 shares of common stock. The warrants exchanged in this transaction were subsequently cancelled and terminated.

The Company re-measured the fair value of the exchanged warrants immediately prior to the exchange and recorded a $3.0 million derivatives loss on the statement of operations and a corresponding increase to the warrant liability on the balance sheet. The fair value of the warrants immediately prior to the exchange was equivalent to 80,857 shares of common stock at the Company’s closing stock price of $43.75 on August 9, 2017, the day before execution of the exchange. As a result of the exchange, the Company recorded the settlement by removing the derivative liability related to the exchanged warrants and recorded the issuance of common stock for $3.5 million.

Following the warrant exchange, there were additional warrants, dated May 9, 2014, to purchase shares of common stock that remain outstanding (“Outstanding 2014 Warrants”). As a result of the Company’s issuance of common stock in exchange for certain of the liability warrants, the exercise price of the Outstanding 2014 Warrants was adjusted downwards from $96.75 per share to $20.75 per share and additional warrants were issued such that the Outstanding 2014 Warrants were exercisable for an aggregate of 1,941 shares of common stock.

Warrant Cancellation

In the fourth quarter of 2017, the Company entered into warrant cancellation agreements with certain holders of the Outstanding 2014 Warrants to cancel and terminate such warrants for total cash consideration of $40 thousand. As of December 31, 2017, the remaining Outstanding 2014 Warrants were exercisable for an aggregate of 537 shares of common stock.

During the year ended December 31, 2018 the Company entered into warrant cancellation agreements with certain holders of the Outstanding 2014 Warrants to cancel and terminate such warrants for total cash consideration of $14 thousand. As of December 31, 2018, the sole remaining Outstanding 2014 Warrants were exercisable for an aggregate of 307 shares of common stock.

Warrant Amendments

In May 2018, the Company entered into a warrant amendment agreement with the sole remaining holder of an Outstanding 2014 Warrant (the "Warrant Amendment"). The warrant holder received cash compensation of $19 thousand and a 2 year extension of warrant term in exchange for the removal of all anti-dilution provisions except those for stock splits, reverse splits or stock dividends. As a result of the amendment, the Company reclassified the remaining 2014 warrants valued at $1 thousand to stockholders' equity (see Note 10).

In September 2018, the Company entered into the Ladenburg Warrant Amendment. As a result of the Ladenburg Warrant Amendment, the Company reclassified the 2018 Warrants valued at $14.7 million to stockholders' equity (see Note 10).

13. EMPLOYEE BENEFIT PLAN

In November 2006, the Company adopted a 401(k) plan (the "Plan") covering all employees. Employees must be 21 years of age in order to participate in the Plan. Under the Plan, the Company has the option to make matching contributions. In the second quarter of 2018 the Company revised its 401(k)-matching policy to move from share matching to cash-based matching. For the year ended December 31, 2018, the Company made matching contributions in the form of cash and shares of the Company's common stock. For the year ended December 31, 2017, the Company made matching contributions in the form of shares of the Company's common stock only. For the years ended December 31, 2018 and 2017, the Company issued 440, and 3,933 shares of its common stock, respectively, with related fair values of $6 thousand and $183 thousand respectively, which were recorded as expense in the statement of operations.

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14. INTELLECTUAL PROPERTY LICENSE

In July 2007, the Company entered into a worldwide exclusive license (the "BCH License") for patents co-owned by Boston Children's Hospital ("BCH") and the Massachusetts Institute of Technology initially covering the use of biopolymers to treat spinal cord injuries, and to promote the survival and proliferation of human stem cells in the spinal cord. During 2011, the BCH License was amended, and the Company obtained additional rights for use in the field of peripheral nerve injuries. The BCH License, as amended, has a 15 year term, or as long as the life of the last expiring patent right thereunder, whichever is longer, unless terminated earlier by the licensor, under certain conditions as defined in the related license agreement. In connection with the BCH License, the Company paid an initial $75 thousand licensing fee and is required to pay certain annual maintenance fees, milestone payments and royalties. License fees are capitalized and the gross total at December 31, 2018 and 2017 was $200 thousand (see Note 4). The Company accounts for milestone payments, maintenance fees and royalties when they become due and payable. The Company did not pay any milestone payments for the year ended December 31, 2018. For the year ended December 31, 2017, the Company expensed milestone payments of $175 thousand.

15. COMMITMENTS AND CONTINGENCIES

Leases

On November 30, 2011, the Company entered into a commercial lease for 26,342 square feet of office, laboratory and manufacturing space in Cambridge, Massachusetts (as amended on September 17, 2012 and October 31, 2017, the "Cambridge Lease"). The term of the Cambridge Lease is 6 years and 3 months, with one 5 year extension option. On August 21, 2017, the Company exercised its option for the 5-year extension on the Cambridge Lease. The 5- year renewal lease term commences on November 1, 2018 and ends on October 31, 2023. The terms of the Cambridge Lease require a standby letter of credit in the amount of $311 thousand.

On March 31, 2016, the Company entered into a short-term lease, to sub-lease 5,233 square feet of its facility (the "2016 Sublease"). The 2016 Sublease term was from April 1, 2016 through January 31, 2017. In connection with the 2016 Sublease, the Company received sublease income for the year ended December 31, 2017 of $26 thousand, which was recorded as an offset to rent expense.

On June 13, 2017, the Company entered into a new short-term lease, to sub-lease 5,233 square feet of its facility (the "Moderna Sublease"). The lease term was from July 1, 2017 through October 26, 2018. On June 19, 2017, the Company received a $55 thousand security deposit under the terms of the Moderna Sublease. In conjunction with the assignment of the Cambridge Lease on May 3, 2018 further described below, this security deposit was transferred to the third party that assumed the lease. In connection with the Moderna Sublease, the Company received sublease income of $112 thousand for the year ended December 31, 2018, which was recorded as an offset to rent expense.

On May 3, 2018, the Company assigned the Cambridge Lease to a third party who assumed all of the Company's remaining rights and obligations under the Cambridge Lease including the Moderna Sublease. On the same date as the lease assignment, the Company entered into a sublease for 5,104 square feet of space, originally part of the Cambridge Lease, from the third party to which the Company assigned the Cambridge Lease (the "Current Cambridge Lease"). The Current Cambridge Lease commenced on May 3, 2018 and expires October 31, 2023 and contains rent holiday and rent escalation clauses. In connection with the Cambridge Lease Assignment and the Current Cambridge Lease, the $311 thousand standby letter of credit was terminated, and a new standby letter of credit was established for $40 thousand. On November 1, 2018, the standby letter of credit was increased to $60 thousand. The $55 thousand security deposit under the Moderna Sublease was transferred to the third party and $603 thousand of deferred rent was removed from the consolidated balance sheets as of June 30, 2018. The resulting gain was recorded within the consolidated statement of operations and comprehensive loss during the second quarter of 2018. The Company also wrote off certain furniture, fixtures and equipment (including laboratory equipment) and recorded an impairment charge of $48 thousand for the year ended December 31, 2018.

The Company recognizes rent expense on a straight-line basis over the term of the lease and records the difference between the amount charged to expense and the rent paid as prepaid rent or deferred rent liability. As of December 31, 2018, and December 31, 2017, the amount of prepaid rent was $17 thousand and $0, respectively. As of December 31, 2018, and December 31, 2017, the amount of deferred rent liability was $0 and $397 thousand, respectively

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Pursuant to the terms of the non cancelable lease agreements in effect at December 31, 2018, the future minimum rent commitments are as follows:

(In thousands) Year Ended December 31,	
2019	$ 243
2020	375
2021	386
2022	398
2023	339
Total	$ 1,741

Total rent expense for the years ended December 31, 2018 and 2017, including month to month leases, was $837 thousand, and $1.2 million, respectively.

Compensation Commitment

The Company entered into a compensation arrangement with an executive during September 2016 which provided for a future cash payment by the Company to the executive based on the February 13, 2017 stock price of the executive's former employer. The award was earned over a period of 1 year. The expense related to the compensation arrangement was $174 thousand for the year ended December 31, 2017. As of December 31, 2018, there were no outstanding payments to the executive.

Lawsuits with Former Employee

In November 2013, the Company filed a lawsuit against Francis Reynolds, its former Chairman, Chief Executive Officer and Chief Financial Officer, in Middlesex Superior Court, Middlesex County, Massachusetts (InVivo Therapeutics Holdings Corp. v. Reynolds, Civil Action No. 13-5004). The complaint alleged 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 involved approximately $500 thousand worth of personal and/or exorbitant expenses that the Company alleged Mr. Reynolds inappropriately caused it to pay while he was serving as the Company's Chief Executive Officer, Chief Financial Officer, President, and Chairman of the Company's Board of Directors. On December 6, 2013, Mr. Reynolds answered the complaint, and filed counterclaims against the Company and the Company's Board of Directors. The counterclaims alleged 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 sought monetary damages and a declaratory judgment. The counterclaims related to Mr. Reynolds's allegations that the Company and the Company's Board of Directors interfered with the performance of his duties under the terms of his employment agreement, and that Mr. Reynolds was entitled to additional shares upon the exercise of certain

stock options that he did not receive. On January 9, 2014, the Company, along with the directors named in the counterclaims, filed the Company's answer denying that Mr. Reynolds was entitled to any relief. 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. In July 2018, the parties reported the case as settled to the Court.

Vendor Dispute

In July 2018, the Company entered into a settlement agreement with a former vendor under which the vendor agreed to pay the Company $1.2 million, of which the full amount has been paid and is included in other income on the statement of operations and other comprehensive loss.

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16. RESTRUCTURING

In August 2017, the Company implemented a strategic restructuring. In conjunction with the strategic restructuring, the Company completed a reduction in force eliminating approximately 39% of its workforce.

The Company did not record any restructuring expenses for the year ended December 31, 2018. For the year ended December 31, 2017, the Company recorded $898 thousand in restructuring expenses, including employee severance benefits and related costs, as well as a write-off of certain fixed assets.

The following table summarizes the restructuring costs by category for the periods indicated:

	Year Ended December 31, 2017		
		Non-Cash	
(In thousands)	Cash	(1)	Total
Research and development	$ 669	$ 41	$ 710
General and administrative	188	—	188
Restructuring Costs	$ 857	$ 41	$ 898

(1) The non-cash restructuring expenses represent write-offs of certain fixed assets in connection with the restructuring. The write-offs were recorded as a charge to research and development expense on the statement of operations.

The following table summarizes the restructuring reserve for the periods indicated:

(In thousands)	December 31, 2018	December 31, 2017
Restructuring reserve beginning balance	$ 348	$ —
Cash restructuring expenses incurred during the period	—	857
Amounts paid during the period	(348)	(509)
Restructuring reserve ending balance	$ —	$ 348

17. RELATED PARTY TRANSACTIONS

In January 2017, the Company entered into a consulting agreement with Dr. Robert Langer, a member of the Company’s Scientific Advisory Board, who at the time of entering into the consulting agreement was a holder of over 5% of the Company’s common stock, for certain consulting services. Dr. Langer was one of the original co-founders of the Company. Pursuant to the terms of the agreement, the Company initially agreed to pay Dr. Langer $250 thousand per year in consulting fees, but that amount was reduced effective October 2017 to $100 thousand per year in consulting fees. For the years ended December 31, 2018 and 2017 the Company paid Dr. Langer $83 thousand and $204 thousand in consulting fees respectively.

Dr Langer holds less than 5% of the Company’s common stock as of December 31, 2018.

18. SUBSEQUENT EVENTS

In connection with the employment agreement for the Company's new Chief Finance Officer and Treasurer, the Company granted a non-statutory stock option to purchase up to 90,000 shares of the Company’s common stock, as an inducement grant outside of the Company’s 2015 Stock Incentive Plan pursuant to Nasdaq Listing Rule 5635(c)(4).

On March 1, 2019, the Company paid off the remaining outstanding MassDev loan payable amounts.

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

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of the Company's Disclosure Controls

Our management, with the participation of its Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of its disclosure controls and procedures as of December 31, 2018. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of the Company's disclosure controls and procedures as of December 31, 2018, the Company's Chief Executive Officer and Chief Financial Officer concluded that, as of such date, the Company's disclosure controls and procedures were not effective due to deficiencies in internal control over financial reporting as discussed and defined in "Management's Annual Report on Internal Control over Financial Reporting" referred to below.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) for the Company. Our internal control over financial reporting is designed to provide reasonable assurances regarding the reliability of financial reporting and the preparation of our consolidated financial statements in accordance with U.S. generally accepted accounting principles, or GAAP, and includes those policies and procedures that:

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

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and

- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

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

Our management conducted an evaluation of the effectiveness of the Company's internal control over financial reporting based on the framework in "Internal Control — Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, management concluded that our internal control over financial reporting was not effective at December 31, 2018 because of the material weakness described below.

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Based on the COSO criteria, management identified control deficiencies that constitute a material weakness. A "material weakness", as defined by COSO, is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is more than a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected in a timely manner. Management has identified the following deficiencies in our internal control over financial reporting:

- We did not perform a timely and ongoing entity-level risk assessment to identify and assess changes that could significantly impact the system of internal control over financial reporting. New risks arising from changes to certain of our systems, personnel and processes during the year were not identified, assessed and responded to in a timely manner. The lack of a timely and ongoing entity-level risk assessment constituted an internal control design deficiency, which resulted in more than a remote likelihood that a material error would not have been prevented or detected.

- We did not follow appropriate system development lifecycle controls when implementing a new general ledger accounting system in July 2018. Furthermore, we did not conduct continuous risk assessments and monitoring activities, or adequately identify and analyze risks of financial misstatements due to error and/or fraud and, therefore we did not adequately identify and assess the changes that impacted the system of internal control. Additionally, we did not have adequate information technology general controls ("ITGCs") in the areas of user access, change management, and computer operations over certain systems that support the financial reporting process. These deficiencies could result in occurrences of unmonitored access to certain applications, unsupervised changes being implemented, and an absence of information to enable us to implement adequate detective controls. These deficiencies may have adversely impacted the functionality of key applications, and the integrity of underlying data that supports the effectiveness of system-generated data and reports used in financial reporting.

- We did not formally develop or perform evaluations to ascertain whether the components of internal control were present and functioning through the period ended September 30, 2018. This affected our ability to identify, evaluate and communicate internal control deficiencies in a timely manner to those parties responsible for taking corrective action, including senior management and the Board of Directors, as appropriate. The lack of timely evaluations of the components of internal control constituted an internal control design deficiency, which resulted in more than a remote likelihood that a material error would not have been prevented or detected.

We have not had sufficient time to fully remediate all the aforementioned deficiencies and therefore, some of the control deficiencies continued to exist as of December 31, 2018. We believe the control deficiencies described herein, when aggregated, represent a material weakness in our internal control over financial reporting at December 31, 2018 because such deficiencies result in a reasonable possibility that a material misstatement in our annual or interim consolidated financial statements may not be prevented or detected on a timely basis by our internal controls. As a result of this assessment, we have therefore concluded that our internal controls over financial reporting were not effective at December 31, 2018.

Despite the existence of the material weakness described above, our consolidated financial statements are presented fairly, in all material respects, in conformity with accounting principles generally accepted in the United States of America.

Changes in Internal Control Over Financial Reporting

Other than as described above in “Management’s Annual Report on Internal Control over Financial Reporting,” there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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Plan for Remediation

We are currently taking actions to remediate the deficiencies in our internal controls over financial reporting and are implementing additional processes and controls designed to address the underlying causes associated with the above-mentioned deficiencies. We are committed to remediating the deficiencies described above and developed and began remediation efforts during the year ended December 31, 2018 and will continue such for 2019. During the year ended December 31, 2018 and continuing into 2019, our internal control remediation efforts include the following:

- In the three months ended December 31, 2018, we performed an entity-level risk assessment to evaluate the implication of relevant risks on financial reporting, including the impact of potential fraud-related risks and the risks related to non-routine transactions, if any, on internal control over financial reporting. We plan to make this a continuous process in 2019 and thereafter.

- We are exploring opportunities to implement a new general ledger accounting system that would address some of the limitations inherent in the current general ledger accounting system. We intend to engage information technology and financial reporting personnel to perform a risk and control assessment of the new general ledger accounting system as part of the system selection process. In the interim, we will also design and identify sufficient compensating controls to address the limitations inherent with our existing general ledger accounting system. If we decide to forgo a new general ledger accounting system implementation, sufficient compensating controls will be performed indefinitely.

- In December 2018, we engaged a third-party to perform an evaluation to ascertain whether the components of internal control were present and functioning throughout the three months ended December 31, 2018. We plan to make this a continuous process through 2019 to ensure that internal control deficiencies are evaluated and communicated in a timely manner to those parties responsible for taking corrective action, including senior management and the Board of Directors, as appropriate. The third-party will also assist management in designing and evaluating the ITGCs over all financially-significant systems.

We believe these actions will be effective in remediating the deficiencies described above. As we continue to evaluate and work to improve our internal control over financial reporting, we may determine to take additional measures to address the deficiencies or determine to modify the remediation plan described above. Until the remediation steps set forth above are fully implemented and operating for a sufficient period of time, the material weakness described above will continue to exist.

Item 9B. OTHER INFORMATION

None.

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item is incorporated herein by reference from the portions of the definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days following the end of our 2018 fiscal year under the heading “Corporate Governance”.

Code of Ethics

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

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated herein by reference from the portions of the definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days following the end of our 2018 fiscal year under the headings “Executive Compensation” and “Compensation Tables.”

Pay Ratio

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information under this item.

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

The information relating to security ownership by certain beneficial owners and management is incorporated herein by reference from the portion of the definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days following the end of our 2018 fiscal year under the heading “Stock Ownership of Management and Principal Shareholders."

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides certain information about shares of our common stock that may be issued under our existing equity compensation plan as of December 31, 2018, which consists of our 2007 Equity Incentive Plan, 2010 Equity Incentive Plan, 2015 Equity Incentive Plan, and Employee Stock Purchase Plan or other equity compensation plans not approved by security holders.

The inducement grant that was approved by our Board of Directors on December 17, 2018 and awarded to our new Chief Financial Officer is excluded from the table below, as the effective date of the grant was January 14, 2019. The terms and conditions of the plan include the terms and conditions of the Nonstatutory Stock Option Agreement included as Exhibit 10.32 of this Annual Report on Form 10-k.

Plan Category	(a) Number of securities to be issued upon the exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)
Equity compensation plans approved by security holders	65,099	$ 84.96	188,552
Total	65,099	$ 84.96	188,552

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

The information required by this Item is incorporated herein by reference from the portion of the definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days following the end of our 2018 fiscal year under the headings “Certain Relationships and Related Transactions” and "Corporate Governance".

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item is incorporated herein by reference from the portion of the definitive Proxy Statement to be filed with the Securities and Exchange Commission within 120 days following the end of our 2018 fiscal year under the proposal heading “Ratification of Appointment of Independent Registered Public Accounting Firm”.

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PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Financial Statements.

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

Financial Statement Schedules.

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

Exhibits.

The following is a list of exhibits filed as part of this Annual Report on 10-K.

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated October 4, 2010, by and between Design Source, Inc. and InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 2.2 to the Company's Current Report on Form 8 K, as filed with the SEC on October 6, 2010).
2.2	Agreement and Plan of Merger and Reorganization, dated as of October 26, 2010, by and among InVivo Therapeutics Holdings Corp. (f/k/a Design Source, Inc.), a Nevada corporation, InVivo Therapeutics Acquisition Corp., a Delaware corporation and InVivo Therapeutics Corporation, a Delaware corporation (incorporated by reference from Exhibit 2.1 to the Company's Current Report on Form 8 K, as filed with the SEC on November 1, 2010).
3.1	Articles of Incorporation of InVivo Therapeutics Holdings Corp., as amended (incorporated by reference from Exhibit 3.1 to the Company's Quarterly Report on Form 10 Q for the quarter ended June 30, 2016, as filed with the SEC on August 4, 2016).
3.2	

	Amended and Restated Bylaws of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, as filed with the SEC on May 6, 2016).
3.3	Certificate of Change Pursuant to NRS 78.209 filed with Nevada Secretary of State, dated April 13, 2018 (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on April 16, 2018).
3.4	Certificate of Amendment to Articles of Incorporation of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC June 1, 2018.)
4.1	Specimen Common Stock Certificate (incorporated by reference from Exhibit 4.8 to the Company's Annual Report on Form 10_K for the fiscal year ended December 31, 2011, as filed with the SEC on March 15, 2012).
4.2	Warrant dated October 5, 2012 issued to Massachusetts Development Finance Agency (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8_K, as filed with the SEC on October 9, 2012).
4.3	Form of Warrant of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on May 6, 2014).
4.4	Form of Warrant Agreement (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K, as filed with the SEC on March 3, 2016).
4.5	Form of Series A Warrant (incorporated by reference from Exhibit 10.35 to the Company's Registration Statement on Form S-1/A (File No. 333- 224424) as filed with the SEC on June 14, 2018).
4.6	Form of Series B Warrant (incorporated by reference from Exhibit 10.35 to the Company's Registration Statement on Form S-1/A (File No. 333- 224424) as filed with the SEC on June 14, 2018).

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4.7		Amendment to Warrant Agency Agreement, by and between InVivo Therapeutics Holdings Corp. and Continental Stock Transfer & Trust Company, as Warrant Agent, dated September 27, 2018 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on September 28, 2018).
10.1*		InVivo Therapeutics Corp. 2007 Employee, Director and Consultant Stock Plan (incorporated by reference from Exhibit 10.9 to the Company's Current Report on Form 8_K, as filed with the SEC on November 1, 2010).
10.2(i)	*	Form of Incentive Stock Option Agreement by and between InVivo Therapeutics Corp. and participants under the 2007 Employee, Director and Consultant Stock Plan (incorporated by reference from Exhibit 10.11(i) to the Company's Current Report on Form 8_K, as filed with the SEC on November 1, 2010).
10.2(ii)*		Form of Non_Qualified Stock Option Agreement by and between InVivo Therapeutics Corp. and participants under the 2007 Employee, Director and Consultant Stock Plan (incorporated by reference from Exhibit 10.11(ii) to the Company's Current Report on Form 8_K, as filed with the SEC on November 1, 2010).
10.3*		InVivo Therapeutics Holdings Corp. 2010 Equity Incentive Plan, as amended (incorporated by reference to Appendix A to the Company's Schedule 14A Proxy Statement, as filed with the SEC on April 19, 2013).
10.4(i)*		Form of Incentive Stock Option Agreement by and between InVivo Therapeutics Holdings Corp. and participants under the 2010 Equity Incentive Plan (incorporated by reference from Exhibit 10.12(i) to the Company's Annual Report on Form 10_K for the fiscal year ended December 31, 2010, as filed with the SEC on March 24, 2011).
10.4(ii)*		Form of Non_Qualified Stock Option Agreement by and between InVivo Therapeutics Holdings Corp. and participants under the 2010 Equity Incentive Plan (incorporated by reference from Exhibit 10.12(ii) to the Company's Annual Report on Form 10_K for the fiscal year ended December 31, 2010, as filed with the SEC on March 24, 2011).
10.5		Form of Scientific Advisory Board Agreement entered into by InVivo Therapeutics Corp. (incorporated by reference from Exhibit 10.13 to the Company's Current Report on Form 8_K, as filed with the SEC on November 1, 2010).
10.6		Exclusive License Agreement dated July 2007 between InVivo Therapeutics Corporation and Children's Medical Center Corporation (incorporated by reference from Exhibit 10.1 to Amendment No. 2 to the Company's Quarterly Report on Form 10_Q/A for the quarter ended March 31, 2011, as filed with the SEC on July 18, 2011).
10.7		Amendment One to the Exclusive License, dated May 12, 2011, by and between Children's Medical Center Corporation and InVivo Therapeutics Corporation (incorporated by reference from Exhibit 10.22 to the Amendment No. 4 to the Company's Registration Statement on Form S_1/A (File No. 333_171998), as filed with the SEC on July 19, 2011).
10.8		Amendment Two to the Exclusive License, dated August 29, 2017, by and between Children's Medical Center Corporation and InVivo Therapeutics Corporation (incorporated by reference from Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q/A for the quarter ended September 30, 2017, as filed with the SEC on January 3, 2018).
10.9		Form of Indemnification Agreement (for directors and officers) (incorporated by reference from Exhibit 10.19 to the Company's Registration Statement on Form S_1 (File No. 333_171998), as filed with the SEC on February 1, 2011).
10.10		Lease Agreement, dated November 30, 2011, between InVivo Therapeutics Corporation and RB Kendall Fee, LLC (incorporated by reference from Exhibit 10.25 to the Company's Registration Statement on Form S_1 (File No. 333_178584), as filed with the SEC on December 16, 2011).
10.11		Lease Guaranty, dated November 30, 2011, by InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 10.26 to the Company's Registration Statement on Form S_1 (File No. 333_178584), as filed with the SEC on December 16, 2011).

10.12	First Amendment of Lease between InVivo Therapeutics Corporation and RB Kendall Fee, LLC, dated September 17, 2012 (incorporated by reference from Exhibit 10.31 to the Company's Annual Report on Form 10_K for the fiscal year ended December 31, 2012, as filed with the SEC on March 12, 2013).
10.13	Second Amendment of Lease between InVivo Therapeutics Corporation and RB Kendall Fee, LLC, dated October 31, 2017 (incorporated by reference from Exhibit 10.13 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, as filed with the SEC on March 12, 2018).

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10.14*	InVivo Therapeutics Holdings Corp. Annual Cash Bonus Plan for Executive Officers (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8_K, as filed with the SEC on March 8, 2012).
10.15	Promissory Note dated October 5, 2012 in favor of Massachusetts Development Finance Agency (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8_K, as filed with the SEC on October 9, 2012).
10.16	Purchase Agreement, dated January 25, 2018, between InVivo Therapeutics Holdings Corp. and Lincoln Park Capital Fund, LLC (incorporated by reference from Exhibit 1.1 to the Company's Current Report on Form 8- K, as filed with the SEC on January 26, 2018).
10.17	Registration Rights Agreement, dated January 25, 2018, between InVivo Therapeutics Holdings Corp. and Lincoln Park Capital Fund, LLC (incorporated by reference from Exhibit 1.2 to the Company's Current Report on Form 8-K, as filed with the Commission on January 26, 2018).
10.18*	InVivo Therapeutics Holdings Corp. Employee Stock Purchase Plan (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8_K, as filed with the SEC on June 16, 2015).
10.19*	InVivo Therapeutics Holdings Corp. 2015 Equity Incentive Plan (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8_K, as filed with the SEC on June 16, 2015).
10.20*	Consulting Agreement, dated June 29, 2017, by and between InVivo Therapeutics Holdings Corp. and Richard Toselli, M.D. (incorporated by reference from Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, as filed with the SEC on August 8, 2017).
10.21*	Letter Agreement, dated December 17, 2017, by and between Mark D. Perrin and InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 10.26 to the Company's Registration Statement on Form S-1/A (File No. 333-222738) as filed with the SEC on February 9, 2018.)
10.22*	Employment Agreement, dated December 18, 2017, by and between Richard Toselli and InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 10.27 to the Company's Registration Statement on Form S-1/A (File No. 333-222738) as filed with the SEC on February 9, 2018.)
10.23*	Consulting Agreement, dated January 3, 2018, by and between Mark D. Perrin and InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 10.28 to the Company's Registration Statement on Form S-1/A (File No. 333-222738) as filed with the SEC on February 9, 2018.)
10.24*	Letter Agreement, dated March 7, 2018, by and between Pamela Stahl and InVivo Therapeutics Holdings Corp (incorporated by reference from Exhibit 10.31 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, as filed with the SEC on March 12, 2018).
10.25*	Consulting Agreement, dated January 19, 2018, by and between Tamara L. Joseph and InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 10.30 to the Company's Registration Statement on Form S-1/A (File No. 333-222738) as filed with the SEC on February 9, 2018.)
10.26	Form of Exchange Agreement, dated as of August 10, 2017, between InVivo Therapeutics Holdings Corp. and certain holders of warrants (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on August 10, 2017).
10.27	Assignment and Assumption of Lease and Consent at Landlord, dated May 3, 2018 by and among Shiseido Americas Corporation, ARE-MA Region No. 59 LLC and InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 10.34 to the Company's Registration Statement on Form S-1/A (File No. 333- 224424) as filed with the SEC on June 14, 2018).
10.28	Sublease, dated May 3, 2018, by and between Shiseido Americas Corporation and InVivo Therapeutics Holdings Corp.(incorporated by reference from Exhibit 10.35 to the Company's Registration Statement on Form S-1/A (File No. 333- 224424) as filed with the SEC on June 14, 2018).
10.29*	Letter Agreement, dated May 7, 2018, by and between Christopher McNulty and InVivo Therapeutics Holding Corp. (incorporated by reference from Exhibit 10.36 to the Company's Registration Statement on Form S-1/A (File No. 333- 224424) as filed with the SEC on June 14, 2018).
10.30*	Amendment to Employment Agreement, by and between InVivo Therapeutics Holdings Corp. and Richard Toselli, dated October 1, 2018 (incorporated by reference from Exhibit 10.1 to the Company's Current

	Report on Form 8-K, as filed with the SEC on October 5, 2018).
10.31*	Employment Agreement, dated December 24, 2018, between the Company and Richard Christopher (incorporated by reference from Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on January 14, 2019).
10.32*	Nonstatutory Stock Option Agreement, dated January 14, 2019, between the Company and Richard Christopher (incorporated by reference from Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on January 14, 2019).

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21.1	Subsidiaries of InVivo Therapeutics Holdings Corp. (incorporated by reference from Exhibit 21.1 to the Company's Current Report on Form 8 K, as filed with the SEC on November 1, 2010).
23.1+	Consent of RSM US LLP
31.1+	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
31.2+	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
32.1+	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
32.2+	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Label Linkbase Document.
101.PRE	XBRL Taxonomy Presentation Linkbase Document.

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

+ Filed herewith.

Item 16. FORM 10-K SUMMARY

None.

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SIGNATURES

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

INVIVO THERAPEUTICS HOLDINGS CORP.

Date: April 1, 2019 By: /s/ RICHARD TOSELLI, M.D
Name: Richard Toselli
Title: President, Chief Executive Officer and Director (Principal Executive Officer)

Date: April 1, 2019 By: /s/ RICHARD CHRISTOPHER
Name: Richard Christopher
Title: Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)

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

Signature	Title	Date
/s/ Richard Toselli M.D Richard Toselli	President, Chief Executive Officer and Director (Principal Executive Officer)	April 1, 2019
/S/ Richard Christopher Richard Christopher	Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	April 1, 2019
/s/ C. Ann Merrifield C. Ann Merrifield	Chair of the Board	April 1, 2019
/s/ Daniel R. Marshak Daniel R. Marshak	Director	April 1, 2019

/s/ Christina Morrison Christina Morrison	Director	April 1, 2019
/s/ Richard J. Roberts Richard J. Roberts	Director	April 1, 2019